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AT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE

ADVISORY COMMITTEE

Tuesday, January 14, 1997

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C O N T E N T S

P R O C E E D I N G S

Open Committee Discussion

Introductory Remarks

DR. PATTERSON: We have a lot on our agenda for today. So, hopefully, we can keep relatively on time. I have been requested, and will honor, the fact of having breaks during the day which we did not have yesterday. I figured that the committee members, if need be, could get up and leave, but unfortunately, we have audio people back there and transcriptionists, et cetera, who cannot leave while we are in session, and therefore, I am allowing the breaks for their benefit. I am sorry I was not quite aware of that. I wasn't thinking about it.

We did discuss two areas of today's agenda yesterday. I am bringing both of these back at this time for anyone to make any additional comments they would like to regarding them since they were on the agenda.

The first was that was scheduled at 10:15 which was on the medical physicists. The other part was the discussion which was scheduled for the afternoon on additional clinical image review and examinee notification. If there are any further comments on either one of these areas, I would like to have them at this time.

Yes, Cass.

MS. KAUFMAN: I realize we are beating a dead horse here, but I just want to make one very quick point. Because I have thought a bit about what bothers me about not requiring more experience for the medical physicists, I guess what bothers me is that we say for the technologists, they have to do so many supervised examinations, and for the radiologists, they have to interpret so many images under direct supervision.

We would never say that a technologist could just repeat mammograms on the same patient over and over and over again and that that would be sufficient experience, nor would we say an interpreting physician could read the same film over and over again and that that would provide sufficient experience.

So it concerns me that if we say that they only have to do three tubes or something like that as initial experience and, in fact, it could be the same tube, we are not referencing if we take out any deletion to facilities. Then, what we are actually saying is that it is so easy to do the survey that, if you see one, eventually you can do it, and I don't think that is the case. I think it is more difficult to do that, and that in any field, experience is the name of the game, and that the more you do, the better you are at it.

So I am just making another comment about why I think there is a requirement to see a number of facilities under the initial experience requirement.

DR. PATTERSON: Okay. I just have one question to ask you. If the patient comes back for additional films or for a six-month follow-up, the tech can't count that? I am sorry. I shouldn't have done that.

MS. KAUFMAN: No, no. Under the initial experience, I think they could, but how many do we say that they need to do? I mean, it is not one patient. It is a lot of patients.

DR. PATTERSON: I was just asking.

Any other comments about either one of those areas?

[No response.]

DR. PATTERSON: Then, we will start this morning, as promised, on the quality standards on the equipment, and I am hoping the equipment manufacturers are back there this morning. I know some of them weren't able to come back today.

This is Section 900.12(b), and this is on page 14915 to 19, and we have Ed Hendrick and Joel Gray.

I'm sorry. Before you start, Charles?

MR. SHOWALTER: Yes, just a quick comment that we are concerned about some of the comments and the comments being how prescriptive the equipment section is. We are concerned about that from two points of view. One is, is it overly prescriptive in principle, and secondly, we are concerned about the comments that we got the last time we went through OMB on this very subject.

We are concerned when we go back for our review this time, are we going to get the same comments and is it going to present us a difficulty.

So any advice that the committee can give us on approaches to not being over-prescriptive would be really appreciated.

Quality Standards-Equipment

DR. HENDRICK: I am going to begin. If you want to get oriented, I am going to start on page 14915 of the Federal Register. It is at the bottom of the third column on page 915.

Equipment is under (b), and then it is numbered with Arabic numerals (1) through (2). I am going to take the first eleven of those. I am not going to keep repeating this (b), but I will refer to (1), (2), (3), and (4), which are the Arabic numerals, and then, under those, there is (i), (ii), (iii), (A), and (B).

Also, to orient you in terms of the comments, for those of you who have your notebooks on comments, the comments on equipment begin on page 161. I will be switching back and forth between those and then try to bring in the equipment questions that are listed in the document that was sent out to committee members.

So, to begin, I do want to raise a general question to the committee, the advisory committee, and that is, one of the comments in the general category suggested that all detailed equipment requirements be placed in a guidance document rather than regulations, and that the regulations have essential requirements such as the equipment should be dedicated to mammography, which I think we would all agree is an important essential.

There may be a couple more that we want to throw in there as essential, like having adequate appropriate-sized image receptors and things like that, maybe even having moving grids, but to take much of the equipment specification that is currently in the regulation, take it out of regulation and move it to a guidance document.

Is there any general comment, any comment on that proposal?

Cass.

MS. KAUFMAN: Well, I just want to remind the committee that guidance documents are not enforceable. They are strictly recommendations, and so, if it is in a guidance document, it does mean that we cannot require it. So we just need to keep that in mind when we go through each item.

So, for example, you mentioned moving grids which is a requirement, and I think we would all agree that at least having a grid is certainly essential for mammography. If you put that in a guidance document, it means we could not enforce it. We could not require a facility to have that.

DR. HENDRICK: Right .

Penny?

MS. BUTLER: I would like to ask the FDA. There was some discussion last spring, I think, about possibly taking some of these things that we had discussed and exploring the possibility of putting them in the Federal X-ray performance standards so they apply to the manufacturer of new equipment.

I think a lot of these items in here are very valuable, but I think the appropriate place for them would be in that sort of thing.

MR. SHOWALTER: That remains an option.

There is one ongoing effort w ithin the organization right now to try to clean up the beam limitation requirement and to make it what would be effectively consistent with the current ACR manual to allow full exposure of the film. That is the current, only ongoing effort, but part of that is a resource issue because there are very, very limited resources right now within the center devoted with anything to do with enforcing the Federal performance standard, changing requirements, changing standards.

It would require center management t o devote those resources to it. I think it remains an option. There is an ongoing discussion that has just started right now about radiation control within CDRH and the necessary resources and the necessary activities. This certainly could be added to that mix. So I think that is a real possibility. If that is what the committee wants to recommend, that is fine.

DR. HENDRICK: One of the possibilities would be to take those items that are recommended 5 years after implementation and 10 years after implementation of the final rules as the things that might be considered manufacturer standards rather than site or facility standards.

MR. SHOWALTER: Yes.

I should make one more comment, and that is that we have much more latitude under MQSA to specify standards than we do under the Radiation Control Act. The Radiation Control Act requires performance standards, and they need to be related to radiation safety. If it doesn't meet that test, it can't be done under the Radiation Control Act.

DR. HENDRICK: Yes.

Dan?

DR. KOPANS: Just a general comment. I support the interest in trying not to be too prescriptive. My concern has to do with advancing the development of mammographic systems, and I can see the potential if you define things in too much detail that it will stifle potential future development.

Dr. Houn has reassured me that that won't happen and that there will be a mechanism to move new ideas through quickly, but until I see that in writing, and we may have it in writing, and it is clear it will be a 30-day review or something like that, I think it is dangerous to define things in too much detail unless it is absolutely necessary.

DR. HENDRICK: There are a few specific examples when we get into the details where it would pose a problem for, say, full-field digital the way it is written.

Cass?

MS. KAUFMAN: I don't know what section it is, but there is something in the regulations that does specifically say that FDA can make variances to this to allow for progress of science. I forget the exact section, but there is a provision in here for that.

My question to Charlie is, Charlie, you said it can only be related to radiation safety. So does that mean, for example, grids, which really are image quality and not radiation safety, moving grids could not be a part of that or like, for example, a minimum SID?

Secondly, realistically, what kind of a time frame would we be looking at for getting something into the code?

MR. SHOWALTER: Certainly, you are looking at a longer time frame, to take the second question first. You are looking at a longer time frame because no proposal has been made under PL 9602. The first step would be to go through Roland's committee, the TEPRSSC committee, and present such a proposal, much as we have done here under MQSA.

There would have to be the proposal, then the analysis of comments, the same process that we are going through here, except under the authority of the Radiation Control Act. So you are looking at several years down the road for that process to be completed.

Then it would apply to equipment manufactured after the effective date, and so it would have no impact on the installed base. That is the major difference in a standard under MQSA and a standard under PL 9602, and that is neither good nor bad. It is just different.

Now, to address the first point, a grid or a minimum SID, a minimum SID is arguably radiation-related because you are talking about a does issue. The shorter that you allow the SID, potentially, arguably, the higher dose you are allowing. That certainly could be controlled in other ways by having a dose limit.

So we haven't explored in ultimate detail with counsel exactly what would or would not be allowed under radiation control, and it depends on the arguments that you want to make for or against a particular requirement and whether you want to cover it and how liberal counsel will let us be in terms of making those arguments and, again, how successful we are with the comments.

We may get comments that say this is stupid, thi s is not a radiation control issue, this is a design issue and you shouldn't be doing it under PL 9602. The thing I think about right off is the angle of rotation of the gantry. That is something that is clearly not doable under the Radiation Control Act.

Where the lines are in between is debatable, and certainly, we could have some of that debate here if the committee desired.

DR. HENDRICK: Yes, Elizabeth.

DR. PATTERSON: To address Dr. Kopans' concern, that would fall, I believe, under the alternative standards. My question, maybe to clarify at least for all of us, what is the time frame that it would take for an alternative standard for something like for research? Could you, by any chance, respond to that, either Flo or Charles?

DR. HOUN: I am just checking to see if an actual proposal time limit was set. I am going to look and see.

DR. PATTERSON: Okay.

DR. HENDRICK: Yes, Dan.

DR. KOPANS: The other concern I have with that, of course, is the cost to the manufacturer, for example. A lot of the changes, in fact, they may not see as necessarily beneficial if they have to put any money into it.

Just as an example, in (A) at the top of page 14916, "The gantry assembly shall be capable of being rigidly fixed..." and so on, "...the gantry shall not move without operator intervention," we are already working on tomography using a conventional mammographic system and a

digital detector, and someone could arguably say you can't do that because it would be a mechanical motion.

I am just, again, con cerned, how expensive would it be for the manufacturer to go back to FDA and get a variance or whatever it is you are going to call it. I think those are the issues that concern me.

DR. HENDRICK: As we go through these, I would suggest keeping open the option of putting these into a guidance document rather than regulation.

I would also suggest keeping open the suggestion which was actually one of the comments that suggested that the equipment requirements be made to apply to manufacturers of equipment for items manufactured beyond a specific date, and especially the items that are 5 years and 10 years after regulation. Let's put them to the test and see if they would be better made as equipment mr requirements.

Joel?

DR. GRAY: I would like to ask for a clarification before we go on. Again, we are talking about facility standards here. Now, we specify in here that by the year, whatever it is going to be, the equipment has to do thus and so. The gantry has to rotate 375 degrees or something. That becomes a requirement on the facility, but what if the facility cannot buy equipment, the manufacturers decide not

to make it? They cannot buy equipment like that. How do we get it back to the manufacturers if it is not incumbent upon them?

DR. HENDRICK: That is a good point.

I think as far as we can tell, most equipment currently manufactured does not have a problem meeting any of the things that are specified here, but that is certainly a theoretical possibility. If equipment were not available that did that, I suppose we would get into regulatory discretion. You obviously can't hold facilities responsible for having something that isn't available.

DR. GRAY: But to me, that raises the question as to why we are writing it into these regulations in the first place if these are facilities standards. They should be going someplace else.

DR. HENDRICK: While the scenario you raise is a theoretical possibility, I doubt seriously that it is a real possibility.

If we wind up writing detailed specifica tions here for equipment, my guess is that there will be equipment available that will meet all of the requirements.

DR. GRAY: But the real possibility is that the costs to facilities will be much higher because it will be required of every facility at a certain date to have

equipment that performs as specified in this document, as opposed to requirements on manufacturers that equipment they sell after a certain date would have to meet these requirements.

DR. HENDRICK: There is no question that the financial impact is much greater if you promulgate a rule under this authority that applies to facilities because then the facility is obliged to deal with upgrading or replacing their equipment --

DR. GRAY: Right.

DR. HENDRICK: -- to get equipment that meets this by a certain date. Whereas, they are not under that same obligation if it is a manufacturing standard.

DR. GRAY: So the impact of the standards is quite different in terms the cost to facilities.

DR. HENDRICK: The impact is quite different , and it is that judgment that we are asking for help on from the committee -- this is obviously going to be costly -- how much is it worth in terms of forcing facilities to move in the direction and, indeed, to meet some of these requirements by a certain date. That is the real issue on the table, I think.

Ruth, did you have a comment?

MS. McBURNEY: I agree with Joel in that we could probably, instead of saying the facility has to meet this standard for those that are 5 years out and 10 years out, that for new equipment purchased or obtained after this date that it would have to meet these standards.

DR. HENDRICK: Right.

MS. McBURNEY: We have done that in facility regulations in X-ray as well.

Regardless of what you put in the performance standards for manufacturers, you could still do that through this Act in order to make it on the facility, but still apply to only new equipment.

DR. HENDRICK: Why don't we start going through the specific items. Item (1) under Equipment is prohibited equipment which simply says that rad equipment designed for general purpose or special nonmammography procedures shall not be used for mammography.

Does anyone disagree with that? There were comments in this section, but all of the comments were really general comments that said if you do this whole section, it is going to raise costs, and there were probably a half-a-dozen comments about that, but not specifically on the prohibited equipment.

[No response.]

DR. HENDRICK: Okay, so that is fine.

(2) is a gene ral statement. "All radiographic equipment used for mammography shall be specifically designed for mammography and...certified pursuant to 1010.2 of this chapter...," which I assume is the basic Federal performance regs, and it mentions some other requirements.

Anyone have any problems with that?

[No response.]

DR. PATTERSON: Okay.

I think (3) is where we begin to get more specific and more tedious. (3) is motion of X-ray tube receptor assembly. (i) is gantry assembly motion, and there is an (A) and (B).

(A), Dan read to you already, which says it has to be able to be fixed rigidly. (B) says that it has to comply with -- I don't even know what that is -- (b)(2)(A) of this section. Oh, that it shall not fail in the event of power interruption. So, if the power goes off, it still stays rigidly fixed. There were not tremendous comments on this.

Six comments expressed concern that the requirements would be very costly to meet all of these under (3).

Joel, did you have something?

DR. GRAY: What I would like to do is bring to the attention for the record again the recommendation that the committee made previously on several of these items, and under (3), actually, (iv), "Effective October 1, 2005, the system shall provide...," et cetera, we recommended that that be deleted.

DR. HENDRICK: So this is (3)?

DR. GRAY: That section be deleted.

DR. HENDRICK: It is (3)(iv).

DR. GRAY: Right.

DR. HENDRICK: What about the suggestion of making these requirements, (ii) and (iii), manufacturer requirements rather than facility requirements?

MS. McBURNEY: The facility requirements that the new equipment --

DR. HENDRICK: No. What I am suggesting is making them --

DR. HOUN: My caution is that if you are saying making it a suggestion to manufacturers, just like in a guidance document, many of these are already recommended in terms of other documents as guidance to manufacturers, or is the question to put them in, like PL 9602, which this would not be able to as a radiation safety?

DR. HENDRICK: Rig ht. My suggestion would be putting them in the Federal performance requirements for equipment manufacturers, and you are saying you can't do it because it is not a radiation safety issue.

DR. HOUN: Right.

MS. McBURNEY: The alternative would be to have it apply to equipment acquired after that date, but put it on the facility.

DR. HENDRICK: Yes. That would be a third possibility.

MS. McBURNEY: Under the MQSA.

It would have the same effect if it applied to new equipment only.

DR. HENDRICK: Right .

Penny?

MS. BUTLER: If this particular standard, as are many other standards in this document, is already being incorporated in equipment manufactured currently, what use is it to write a standard that says for new equipment purchased after such and such a date, it must meet this thing? Why couldn't it just go

DR. HENDRICK: Charlie?

DR. FINDER: I think one of the things you have to realize is that if it is currently being manufactured, that

doesn't mean that all manufacturers are manufacturing it to the standard, and that you may find that there are some out there that are not. If you are just going to put it in guidance, you may not be able to deal with those, but I understand where you are coming from, and if there is a way to get that to be done, it probably wouldn't be a bad idea.

DR. HENDRICK: Let me just try to summarize our possibilities here. It sounds like one possibility is to leave under (3), (i), (ii), and (iii) as is. Another possibility is the suggestion of Ruth's to make (ii) and (iii) requirements on facilities for equipment purchased after those dates, 5 and 10 years after implementation. The third is to delete (ii) and (iii) and put it in a guidance document.

Is there a comment on the specifics of those?

Rita?

MS. HEINLEIN: I don't think it should be deleted. When we were having this conversation on the equipment, we stressed the importance of being able to rotate the gantry to 180 degrees to facilitate positioning on patients that are kyphotic or have any type of open heart surgery, et cetera, et cetera.

I think we would be making a grave mistake in going in the opposite direction if we took it out. I think

it is very important that equipment is capable of doing that, and I feel like we are rehashing issues that we rehashed ad nauseam when we were discussing the equipment regulations. I think this is something that must stay in there.

DR. HENDRICK: Five comments said this might be relevant to diagnostic equipment, but not screening equipment. Do you agree with that?

MS. HEINLEIN: Surely, if they interview people when they call in to ask if the woman is kyphotic and then put her into a diagnostic category, no, I don't agree with that at all.

DR. HENDRICK: Okay.

Dan?

DR. KOPANS: I am sorry to persist on this, but again, if somewhere we could have clarification of what it will take to modify these, for example, this regulation, I could imagine a screening mammographic system where actually the patient moves around a pedestal that doesn't actually rotate at all. That would be precluded under this regulation. What will it take?

I mean, it is nice to say there will be a mechanism, but what is that mechanism, and how expensive and extensive will it be to get a variance?

DR. HOUN: There is no cost associated other than you have to apply. The actual mechanism is on page 14883 and 4, and it is paperwork to assure that whatever alternative standard you are proposing, the person is rotating, they will accomplish the same thing as if we do have (3).

DR. HENDRICK: Dan, I understand your concerns, but you are talking about unproven, untested research protocols, basically, on new equipment designs. I am more concerned about the 15,000 mammography units out there and how many of those are going to have to be completely replaced if these are put into effect 5 years and 10 years after.

I think both of these are concerns, but I think the main concern has to be how costly are these requirements and how many units would simply not be able to meet them under any kind of modification.

Cass?

MS. KAUFMAN: Well, I was just going to agree with Rita. I mean, we have gone over this and over this, and I specifically remember lengthy discussions when we looked at these regulations before regarding this issue, and both technologists, Margaret and Rita, felt very strongly that this was quite an important aspect.

A lot of this equipment is old and needs to be replaced, anyway, and I am not sure there was one comment from the public on this particular issue.

DR. HENDRICK: There were ma ny comments, actually.

MS. KAUFMAN: On this particular one about the gantry being able to be rotated?

DR. HENDRICK: Yes.

MS. KAUFMAN: Because I haven't seen them. Where are they?

DR. HENDRICK: If you look on page 166 and 167, there is a whole list of comments for (ii) and (iii).

Okay. Is the spirit of the committee to keep (ii) and (iii) and delete (iv)?

Pam? You can use this.

MS. KAUFMAN: If I could just follow up, I mean, it says one comment reported that they keep their radiology equipment for a useful lifetime of between 20 and 25 years. I mean, I don't think any of us think that that is --

DR. HENDRICK: No, the idea isn't to read the specious comments. The idea is to focus on the ones that may have merit.

MS. WILCOX-BUCHALLA: Pam Wilcox-Buchalla, ACR.

I would like to speak to support of Ruth's comment that perhaps you should look at requiring equipment

purchased after a certain date and only have a single date rather than these phase-ins. I am concerned about the implications of cost where some units could be retrofitted at significant expense, and then the facility will still ultimately have to purchase a new unit by the second date. Wherever possible, I think it would be most cost effective to have a single date and date of purchase.

Thank you.

DR. HENDRICK: Yes. Esther?

MS. SCIAMMARELLA: Ed, I think I want to sustain what Rita has been mentioning.

From the consumer perspective, I am very much concerned about what happened with equipment if we don't describe the way it is and establish that we need to protect the consumer.

I think I hear too many cost containments. I am really very concerned about the quality, that the services are there, that we need to be specific about this.

DR. HENDRICK: That is what I am hearing. I don't hear any strong objections to keeping (ii) and (iii).

Rita?

MS. HEINLEIN: Well, I certainly don't object to keeping it, but I think Pam has a wonderful suggestion in

referring it to new equipment and coming up with one date as opposed to this phase-in time.

I mean, when we are talking 5 years, we are actually talking 2002.

DR. HENDRICK: Or 2003.

MS. HEINLEIN: Yes, or 2003. I say why not come up with one date. Even if we make it 2002 or 2003, that is still a pretty long time from now, and if they already have this equipment and it is equipment that doesn't do this, then that is relatively old equipment that does need to be replaced. So they will know, then, that when they are looking for new equipment in another 5 years, what would be required of them. I like that idea of doing one date.

DR. HENDRICK: Penny?

MS. BUTLER: So are you saying, Rita, that the rotation should fall under that category or are you saying keeping the rotation in?

DR. HENDRICK: I think what she is suggesting is that we take (ii) and (iii) and lump them together at 5 years after implementation --

MS. BUTLER: Right.

DR. HENDRICK: -- rather than 5 and 10.

MS. BUTLER: For new equipment?

MS. HEINLEIN: Right. In effect, you are really taking out (ii) and just saying that, in 5 years out, that would have to go 180 and at least 135 for new equipment.

DR. HENDRICK: Are you saying for new equipment manufactured and sold after that date or purchased by facilities after that date?

MS. HEINLEIN: Yes.

DR. HENDRICK: Okay.

MS. BUTLER: After listing to all of the discussions, I would like to support Ruth's proposal and the modification that Pam just brought up.

DR. HENDRICK: So is the committee in general consensus on that? Do you understand what we are talking about doing?

MS. KAUFMAN: My only concern about that is that then you are putting the facilities in the position of maybe keeping an older unit longer than they might ordinarily do.

If we say that they only have to do this if they buy a new unit, then that kind of encourages them not to buy a new unit.

DR. HENDRICK: To not buy a new unit.

MS. KAUFMAN: Yes.

DR. HENDRICK: Possibly.

MR. SHOWALTER: Let me bring up another question, and that is the question of what is a new unit. Is a unit sold from one facility to another, that is, a used unit, in normal parlance? Is that a new unit for the facility?

DR. HENDRICK: Yes. I think we are talking about for the facility; that anything they brought in as additional or replacement --

MS. McBURNEY: Acquired after.

DR. HENDRICK: -- acquired equipment, it would be considered a new unit. Otherwise, you have no possibility of sweeping out the old unit. They can just keep exchanging with each other forever.

[Laughter.]

DR. HENDRICK: Any other comments?

Yes, Florence.

DR. HOUN: Just adding another concern, now you are having a 10-year requirement. I just want to say it looks maybe a little funny to people that if this is something important, essential for quality, you need it in regulation. You want it 10 years from now, but you are concerned about fixing technology. There may be some contradictions with that as well.

DR. HENDRICK: We were actually talking about having a 5-year from the date of regulation, adoption of regulations, that both of these would go into effect.

Okay, that sounds like a reasonable --

MS. KAUFMAN: There is one comment that --

DR. HENDRICK: Is this going to be one of the good comments or one of the bad comments?

MS. KAUFMAN: Well, I am not making value judgment. They are not marked. There is not a little "m" there for meritorious.

One said something about maybe making the statement that there has to be at least one unit in each facility that meets those requirements, so that those patients could be done on that unit.

MS. SCIAMMARELLA: I think, today and yesterday, the concern that we are backwards, it may be my impression that we have been very strict from the beginning. Now we want to modify things. I hear too much about cost. We protecting more the manufacturers and institutions than the consumer. I am a little bit concerned about that.

I think we need to implement the best we can because of the consumer more than the other issues.

DR. HENDRICK: I don't think we are here representing the manufacturers. In fact, manufacturers will

love this, Esther, because it will sell lots of new units if it were as written here.

What we are concerned about is trading off cost and, I think, access in terms of keeping facilities alive.

MS. SCIAMMARELLA: But I think yesterday, Ed, we discussed the issue here. I am not concerned about Washington University. I mean, I am concerned there are people who perform mammography there who will really need to be very concerned. They will need to follow up more. They don't need to enforce the guidelines, but I think it is important that people are clear on the Federal guidelines what they are supposed to do, and I see the improvement.

DR. HENDRICK: Does the FDA have a sense of the committee here?

Okay. Moving on to (4), image receptor sizes. (i) says that, at a minimum, each unit should have an 18-by-24 and 24-by-30-centimeter image receptor size for screen-film, not for digital. Screen-film only. Not for Xerox either.

DR. KOPANS: Would you want to make that just "comparable to" as opposed to "exactly," or does that leave too much leeway?

DR. HENDRICK: We could put in the word "approximately." I don't have any problem with that, but

this is specific to film screen. I don't know of any film screen sizes that are other than these two for mammography.

Penny?

MS. BUTLER: I would just like to give my opinion that I think this is important and we should leave it in.

DR. HENDRICK: Okay.

Rita?

MS. HEINLEIN: I agree. I know that there were some comments saying that could it be changed, just so the facility would make sure that they had both sizes of image receptors available. I agree with Penny. I think it is very important, and I think it should be per unit.

DR. HENDRICK: Okay. So it sounds like we are all in general consensus of agreement about (i).

What about (ii), equipped with moving grids to match all image receptor sizes?

DR. FINDER: Ed?

DR. HENDRICK: Yes.

DR. FINDER: Can I ask a question?

Rita, your last comment, I am just interested why it is important that all the units in a facility be able to do that rather than at least one. How many cancers is that going to pick up?

MS. HEINLEIN: I don't know that I can give you a number as to how many more cancers it is going to pick up, but what it will do is if the facility is busy and they have six large-breasted women coming and it is just before lunch, I will guarantee that what is going to happen is we will just do them in sections in this room because we only have one room that does the large grid.

I have been to many facilities that purchase one large grid for one room, and when things get busy, that is exactly what happens. They just say, "Well, we are going to catch up. So it will be all right. We can just piece them together. Or, what they do is they exclude portions of the breast. I think it is vitally important that they have both size.

DR. HENDRICK: Okay. How about (iii), "Systems used for magnification procedures shall be capable of operation with the grid removed"? There were only a couple of comments on this, and not very strong.

[No comment.]

DR. HENDRICK: Now, (iv) is where we get into -- yes, Joel.

DR. GRAY: (iv), the committee recommended deletion of that the last time we discussed it.

DR. HENDRICK: Okay, and that eliminates the complex and untested performance criteria that are listed here.

DR. GRAY: Yes.

DR. HENDRICK: Are we still in agreement on that?

The real issue here under (iv) is not so much the grid motion shall be impeded when the breast is subject to compression, but I think the real issue is you don't want either residual gridlines or serious grid and homogeneities cast on the images you acquire, and this is probably one of the least likely ways that residual grid lines can occur.

So, if the goal is to have images free of grid artifacts, and that is something that is tested by the medical physicists, I guess I would prefer to leave it to the discretion of the medical physicists to first do the test and do decide when equipment changes are needed because of the results of the tests.

All right. Moving on to (5), the top third of the middle column, beam limitation and light fields, (i), "All systems shall have beam limitation devices that provide means to restrict the useful beams so that the X-ray field can be adjusted to extend beyond the chest wall edge of the image receptor."

There were several comments on this because the language "can be adjusted to" was confusing, and what I would recommend is crossing out "can be adjusted to" and just say "so that the X-ray field extends beyond the chest wall edge of the image receptor." The point is you don't want to cut off any chest wall part of the breast because the X-rays come inside the image receptor, but most units aren't adjustable. They just have a diaphragm that fixes that X-ray field.

Any problems with that revision? That was also suggested by one of the comments, not even mine.

The other question is, at that point, do we want to put in that we don't want the X-ray field to extend more than 2 percent of the SID beyond the chest wall edge, which is certainly in the ACR documents. I can't remember if it is a Federal performance. Yes, it is a Federal performance.

Penny?

MS. BUTLER: It is a Federal performance standard. I mean, do we really have to repeat it here? Can't we just put in a statement that must meet and incite the appropriate part of the X-ray performance standards?

Charlie?

MR. SHOWALTER: Well, yes, you can, but we keep getting conflicting advice on this point, and the advice

that we get from time to time is people don't know what 1020.30 is and 1020.31 is, and if you have a requirement, why don't you just restate it here so it is all in one place.

DR. HENDRICK: I agree with that.

MR. SHOWALTER: I agree that it can be done either way, and it is an issue of clarity. We need advice on how to proceed.

DR. HENDRICK: So I would suggest after the phrase "extends beyond the chest wall edge of the image receptor," put in a comma and then add the phrase "but not by more than 2 percent of the SID," and I think it clarifies that.

You may want to flush the language out a little bit -- or is it "flesh" the language out. Anyway, are we in agreement about that?

[No response.]

DR. HENDRICK: Okay. (ii), "Any mammography system with a light field that passes through the beam-limiting device shall meet the following requirements," and then there is (A) which deals with alignment and (B) which deals with intensity elimination.

Joel?

DR. GRAY: We recommended deleting (B).

DR. HENDRICK: Okay. (A) is tested against in the ACR medical physics procedures, anyway. Do we want to leave it in here as an equipment performance standard since it is a QC performance standard?

Rita?

MS. HEINLEIN: If it is under the ACR, what about those facilities that may be accredited by a different accrediting body? Do they follow those same requirements?

DR. HENDRICK: Well, in actually carrying through the logic here, the ACR document may not be the document adopted by reference after the final rules go into effect, anyway. So that may get lost.

MS. HEINLEIN: Yes.

MS. SCIAMMARELLA: Yes. I think this is a really important point that Ed is bringing up, is it really necessary to have it both in the equipment requirement and in the quality control testing requirement, is it sufficient to have it in one place or the other.

DR. HENDRICK: Cass?

MS. KAUFMAN: Speaking from a regulator's standpoint, that is one of the most frequent complaints is to have regulations in various different parts and to keep referring people to different volumes.

I know at least in California, they really don't like duplicative regulations, but I think for the facilities and the manufacturers and that kind of thing, it really is much easier if they know that they can go to one place and find everything that they need to know.

DR. HENDRICK: Penny?

MS. BUTLER: We just deleted the grid motion section, although it was a little more complex than what you would see in the medical physicist test, which evaluates grid motion.

I would like to sugge st, maybe, pulling out the QC stuff that is in here and keeping it in the QC section.

DR. HENDRICK: The QC section. Do you recall in your view of the QC section, was this in here, the congruence of light field with radiation field?

MS. BUTLER: Yes, and I think it referred back to this section.

DR. HENDRICK: Oh, it referred back to this?

MS. BUTLER: So maybe we should just pull the wording out of here and stick it in the QC section.

DR. HENDRICK: Yes. That is what I would prefer, to make it the QC performance test that gets tested annually.

DR. FINDER: Ed, when you go through this, could you kind of state whether you believe this should be immediate or go into the 5-year?

DR. HENDRICK: We are assuming that everything that doesn't have a date on it is immediate when the final rules go into effect. That is what, I think, the intention of the committee was.

Yes. Penny?

MS. BUTLER: I have another question on (B) which is the light field average illumination. Isn't this currently included in the X-ray performance standards, so equipment has to comply with it, anyway?

MR. SHOWALTER: Yes. That is another case where this has been a requirement since 1974 under the diagnostic X-ray performance standard for a light localizer.

Now, you get into another question of what is a light localizer, and there is at least one machine that provides a light that is not allegedly a light localizer, but it is used for illumination of the breast as an aid in positioning, but it does not represent the X-ray field. That is not a light localizer, and it is not required to meet any particular illuminance level.

DR. HENDRICK: Yes. I think can still agree on removing this since it is covered elsewhere, and also, this isn't rocket science.

MR. SHOWALTER: Right.

DR. HENDRICK: I mean, you know where the image receptor is. Generally, techs know where the breast goes and where the radiation field goes. So this may be overkill.

Ruth?

MS. McBURNEY: It is good to comment on these things that are in the performance standard that is for the manufacturers, and if you want the facility to maintain that level, then it has to be in the facility standards.

MR. SHOWALTER: A very important point.

DR. HENDRICK: That is a good point.

So keeping (B) out of the requirements?

[No response.]

DR. HENDRICK: (iii), effective 5 years after implementation, all mammography systems shall be equipped with light fields that pass through the beam-limiting device and approximate the X-ray field. Do we want to keep that in as a facility requirement?

[Affirmative responses.]

DR. HENDRICK: I guess so.

(iv), effective 10 years after implementation, all systems shall be interlocked to prevent exposure unless appropriate combinations of beam limitation and image receptor sizes are selected.

Joel?

DR. GRAY: Previously, we recommended that items (iv) and (v) be combined, which is the sense of what we are talking about here today of having only one date.

DR. HENDRICK: They both have the same date, don't they?

DR. GRAY: Oh, yes, t hey do. That is correct.

DR. HENDRICK: I was just trying to catch up on the comments and see if there is anything.

MS. BUTLER: Ed, I have a question on this.

DR. HENDRICK: Yes, go ahead.

MS. BUTLER: Now, as we are going through these and we are talking about these items with these specific dates, are we now talking about that these dates apply for new equipment purchased after a certain date? Acquired? Okay, acquired.

DR. HENDRICK: Acquired.

MS. BUTLER: Rather than for all equipment.

DR. HENDRICK: We hadn't clarified that, but is that the intention? That is not the intention? We have no

one on the left and yes on the right, and they are both State people.

MS. BUTLER: Yes over here.

DR. HENDRICK: A yes over here.

MR. SHOWALTER: How about a maybe?

[Laughter.]

MS. KAUFMAN: I think that the goal is to try and get rid of some of this old stuff, and as I said, my concern is that you are encouraging people to keep the old stuff if you tell them that they can continue to use that machine as long as they don't replace it. I think the point was to try and encourage them to update.

DR. HENDRICK: Yes. I guess the question is how much incremental gain in quality do we get by having a requirement that the system have a light field that goes through the X-ray aperture. I think it is probably pretty minimal.

MS. KAUFMAN: Yes. That one, I am not as nervous about, but I think moving grids is a real important one.

DR. HENDRICK: Oh, yes, but moving grids, we have in the regulations when they go into effect.

MR. SHOWALTER: Let me just ask for a clarification here. I took from the initial discussion that, in general, the committee was recommending that

whenever there was a 5-year requirement that it be for equipment acquired after that date. Now, if that is not true consistently, we need to know which is which.

DR. HENDRICK: Right. That is what we are trying to clarify here.

It sounds like for this one, we would have the same condition that, 5 years after implementation, equipment acquired by facilities would have to meet this requirement for at least this, and I think we are taking it on a case-by-case basis.

Roland?

MR. FLETCHER: If you don't specify an end date, you are talking about a beginning date, you are going to introduce a regulatory nightmare where you have got facilities from 5 years forward, some of which will acquire new equipment, some which will do it slowly depending upon costs.

We are saying that we are establishing regulations for quality standards. Yet, we won't have the same standard across the board because you will have facilities with varying age of equipment.

DR. HENDRICK: Yes, that is true, but it is a quality standard on newly acquired equipment.

MR. FLETCHER: What about those who have to go to facilities with older equipment?

DR. HENDRICK: Then they don't necessarily subscribe to that.

The question is, is this something that everyone should have. I mean, do you really have to have a light field that goes through the X-ray aperture that defines exactly where the X-ray field is?

Ruth?

MS. McBURNEY: Just a point. Those facilities with older equipment would still have to meet the existing stuff that is going to go into effect one year out or immediately, and after a certain length of time, as they age, they are not going to be able to meet that.

So, eventually, everybody is going to have to get some sort of new equipment, you would think.

MR. FLETCHER: I have one word for you, "fluoro." I have seen some variations in older equipment that they meet the basic requirements, but there are still some problems.

DR. HENDRICK: The sense I am getting is that this requirement is desirable, not necessarily a requirement, and that is why we are taking this middle ground of requiring it of newly acquired equipment 5 years after regulation.

Penny, did you have another comment?

MS. BUTLER: I was just going to add to Ruth's statement that, hopefully, the QC testing that the physicists and technologists are doing are also going to help push those facilities that have older equipment into purchasing new equipment because they are just not going to be able to pass them.

DR. HENDRICK: Yes, Elizabeth.

DR. PATTERSON: Just to respond to your question that you said a moment ago about it is desirable, but not necessary for quality, which is what I think I just heard you say, my question is why is it in the regs if it is only desirable.

DR. HENDRICK: Well, that is a good question.

DR. PATTERSON: I mean, we are going back to what the comments seem to be saying that we are being very, very prescriptive and too prescriptive.

DR. HENDRICK: Right. I personally think this is getting caught up in the fairly minuscule in terms of importance to have a light field and then have prescriptions on the light field. I don't know. Why don't we ask some of the people who actually do mammography and use the light field.

Rita?

MS. HEINLEIN: I think the light field is very important when you are doing the mammogram. I mean, without the light field, it is difficult to tell if there is any superimposition of other body parts. On the CC, if they have their head turned, it is difficult to tell if there is any hair overlapping with moose on it. It can show up looking like microcalcifications.

DR. HENDRICK: Yes.

MS. HEINLEIN: On obliques, when they are holding the other breast out of the way, you can actually have fingers superimposing the breast tissue posturally.

I think to have a light field is very important. I think the fact that it has to be congruent with the X-ray field is even more important.

DR. HENDRICK: Oh, sure.

MS. HEINLEIN: Too often, you look at it and it looks like it is right, and then the bottom of the breast is cut off, but then you say the light was on it. So I think it is important that the light field be there.

DR. HENDRICK: Okay.

Carl?

DR. D'ORSI: From a radiologist's point of view, we use the light field very critically in localization to make sure that the shadow of the hub obscures the shaft so

that we know we are going in perpendicularly because the path of the X-ray photons are similar to the light photons. So we use that a lot, clinically, for localizations, at least I do.

DR. HENDRICK: Yes. Unfortunately, we are not talking about localization stuff here.

DR. D'ORSI: I think it means the same, units for diagnostic as we use for localizations.

DR. HENDRICK: Yes, okay. All right. Well, I stand corrected.

So do we want to leave this as is?

[Affirmative responses.]

DR. HENDRICK: With the recommendation of merging, is it (iii), (iv), and (v) or just (iv) and (v)?

DR. GRAY: Well, (iv) and (v) are basically the same date, anyway. So there is no reason why we couldn't merge (iii), (iv), and (v) and have a 5-year date on it.

DR. HENDRICK: A 5-year date after implementation for all three?

DR. GRAY: Yes.

DR. PATTERSON: This is new equipment?

DR. HENDRICK: No. This would be leaving it as it is, not new equipment, required of all equipment. This is

what I am hearing, and that is the way we left it the last time.

Is that agre eable to the committee?

[Affirmative responses.]

DR. HENDRICK: Okay. So merging (iii), (iv), and (v), making it 5 years after implementation for all three.

(6), Source-image receptor distance. This is 5 years out for all of these. (i), "Systems designed solely for contact mammography shall have a minimum SID of at least 55 cm." There were a number of comments on this.

One was asking for clarification about what contact mammography means, and I think we could just put in parentheses, they are nonmagnification mammography.

Penny?

MS. BUTLER: Couldn't we just put that in the definitions if it is not there already?

DR. HENDRICK: Yes. That would be fine.

Yes. Dan?

DR. KOPANS: I think it should be defined, but more exactly because all contact mammograms actually give you some magnification.

DR. HENDRICK: Sure.

DR. KOPANS: The only concern I would have about that is if someone develops an X-ray tube that has a smaller

focal spot than what we are using now and has sufficient MA to allow you to do better contact imaging and a shorter SID.

If you are going to make it that specific, should it be for focal spots .3 or larger? I am just concerned with, again, that kind of specific proscription.

DR. HENDRICK: Yes. The whole idea here, I think, is that in the past, cheaper units have dealt with low output by shortening the SID. So it is a combination of errors, actually, and they haven't necessarily strived to get a small focal spot.

I mean, what you are really concerned about here, I think, is the resolution you end up with in the breast, what you are resolving in the breast.

DR. KOPANS: Is there a way of instead of just saying no shorter than 55 centimeters, somehow talking in terms of resolution? I understand why you want to prevent .6 focal spot from being at 50 centimeters, but that, again, is one end of the issue as opposed to the other.

DR. HENDRICK: Right.

Joel?

DR. GRAY: There is also another issue here. As you shorten up the source-to-image distance, you also increase the interval dose to the breast.

DR. HENDRICK: Okay. So it looks like we have a couple of options, leaving this as is with the definition of contact mammography. There was some comments suggesting making it 50 centimeters as opposed to 55 or removing this completely and leaving it as a requirement in terms of system resolution which comes as (8) later on, which is I think the nature of Dan's comment.

Joel?

DR. GRAY: We already recommended deleting the next item (ii).

DR. HENDRICK: Yes.

DR. GRAY: So I would recommend deleting this completely, all of item (6).

DR. HENDRICK: Okay. (ii) requires visual indication of the selected SID which is a minor thing compared to eliminating equipment with shorter-than-a-certain SID, 55 centimeters.

DR. GRAY: Well, but as you stated, the resolution issue will take care of some of this.

MS. KAUFMAN: It won't take care of the dose.

DR. HENDRICK: Yes. Cass' comment is it won't take care of dose.

How does the committee feel?

Penny?

MS. BUTLER: I understand Dan's p oint regarding potentially new technology with smaller focal spots, and you can balance out the resolution of shorter SIDs. I think this can possibly be handled under a variance and that we should keep this the way it is.

DR. HENDRICK: Keeping (i) and eliminating (ii)?

MS. BUTLER: Correct.

DR. HENDRICK: Okay. Any major disagreement with that?

[No response.]

DR. HENDRICK: Okay. "(7), Magnification. (i) Systems used for diagnostic procedures shall have magnification capability available for use by the operator at any time. This specifically is for diagnostic. It is separating screening and diagnostic and applies only to units used for diagnostic mammography."

Joel?

DR. GRAY: I have notes in here that the last time we recommended deleting both (i) and (ii) in this section.

DR. HENDRICK: Okay. Do we want to stick with that?

Joel said we recommended last time deleting all of (7).

Do you have in your notes why we recommended that?

DR. GRAY: No, I don't.

DR. HENDRICK: Penny?

MS. BUTLER: I agree. I think it is micromanaging. I think most of the units do have it available. Certainly, it can be put in the guidance.

DR. HENDRICK: It also is, to some extent, dealt with -- well, no it isn't. If you have magnification, there are resolution requirements on that as well that come into (8), but it doesn't require you to have magnification.

Elizabeth?

DR. PATTERSON: One of our problems with this was we deleted the difference between screening and diagnostic in our definitions and everywhere through there, and I think that was one of the reasons why we decided we didn't want to get back into that.

DR. HENDRICK: Right. Isn't some of this that some radiologists feel that you can do just as good a diagnostic mammography without a high degree of magnification using spot compression with contact mammography? That wasn't the issue? Okay, I don't know.

Are we settled on leaving that out?

Cass?

MS. KAUFMAN: I guess I would just want some confirmation from the radiologists that it is okay to do

diagnostic procedures without the capability of magnification.

I thought what we had decided was to delete (ii), but we were going to keep (i) but make it a facility requirement so they had to have at least one unit. At any rate, I would like to hear what the radiologists think.

DR. HENDRICK: Larry?

DR. KOPANS: I think you can do diagnostic mammography without magnification. What do you all think?

DR. D'ORSI: The systems have gotten, I think, so good now in contact, quite frankly, that what we are finding is magnification really just reduces noise rather than actually increase resolution.

I think we all teach that you can't do diagnostic mammography without magnification. I am not sure that that is absolutely scientifically correct. So I am sort of on the fence, but we don't know if it is absolutely scientifically incorrect. So I think until we know that, the capability should be there for diagnostic work to do magnification.

Part of the problem is, obviously, the increased time and the motion, and that may be part of the reason why you are not appreciating an increase in resolution, but I

think it should be there until we know that it really doesn't make a difference.

DR. HENDRICK: Mike?

DR. LINVER: I would agree, especially for microcalcifications. I think there is certainly a role in our practice and I think in most practices for magnification at this point.

DR. HENDRICK: Okay, but it is one thing to be desirable. It is another thing to have it required in regulations for everybody who does diagnostic.

DR. LINVER: Yes.

DR. HENDRICK: But that is what you are saying is that you think it should be in.

Yes.

DR. MONSEES: I would just like to reiterate that anecdotally at least, without any proof as stringent as Dan would require, I think it really does help dramatically for microcalcifications if you do it properly and if there is no motion. It really is better.

DR. HENDRICK: I didn't even see you behind the post, Barbara.

DR. MONSEES: I know. I am having a hard time.

DR. HEND RICK: Any other comments?

[No response.]

DR. HENDRICK: So is the spirit, then, to leave (i) in there? What about (ii)? Leave that in there?

DR. GRAY: We recommended deleting that before.

DR. FINDER: I just wanted to bring this up. At the last meeting in April, both sections were deleted.

DR. HENDRICK: Yes, that is what Joel had said.

DR. FINDER: Right.

DR. HENDRICK: But we are hearing now that we definitely want to put the first (ii) in. The question is do we want to put both first and second parts in.

Elizabeth?

DR. PATTERSON: One of the comments that was made was that we should use the terminology "systems used for magnification should have" and not use "diagnostic." That was one of the other comments that was made at that time.

DR. HENDRICK: Yes, but --

DR. PATTERSON: I am quoting from the minutes.

DR. HENDRICK: Right, okay. I kind of like the way it is written in the regs better than that.

So leaving both in, is that the spirit of what we would like to do?

MS. KAUFMAN: I wo uld defer to the radiologists on (ii). I don't know.

DR. HENDRICK: Penny?

MS. BUTLER: Well, after listening to the discussion, I think maybe, then, leaving (i) in, but I question the need for specifying the degree of magnification. I would like to again hear from the radiologists on how they feel about it.

DR. HENDRICK: I just have a general comment that one of the problems we see -- well, two problems. One is that a lot of sites used the largest available amount of magnification rather than the one that gives the best resolution in the breast, and those usually are quite different. The second is that in the physics testing, a lot of physicists don't actually test the small focal spot correctly when they test resolution, but that is a separate issue.

Dan?

DR. KOPANS: I agree with you. I have seen situations where too much magnification is used relative to what the system really should be doing, but I guess at some point, you need to say what you said earlier, what is magnification.

I think 1.4 or higher or something like that is not unreasonable. Someone could say we do a 1.2 mag, so we have magnification.

DR. HENDRICK: Right.

DR. KOPANS: I am not sure that is magnification.

DR. HENDRICK: But I think the upper limit was to prevent sites sort of necessarily using the highest available magnification, which would be above to and give terrible results.

So it sounds like we would like to laeve this.

"(8) System resolution. (i) The focal spot shall be such that" -- well, you can read it. It basically says you have to have 11 line-pairs per millimeter with the test pattern oriented with the bars perpendicular to the anodecathode axis which measures the blurring due to the length of the anodecathode, and 13 line-pairs when the bars are parallel to that axis, which measures the width of the focal spot perpendicular to the anodecathode. This is not completely specified because, for this to be a reasonable test, you have to specify the distance of the test pattern from the plane of the breast support, and the ACR specifies 4.5 centimeters above center, left to right, and 2 centimeters in from the chest wall, approximately.

I think if we are going to have this, we need to add that. If we are not going to add that, we need to delete the whole thing.

Comments?

Cass.

MS. KAUFMAN: I thought at an earlier meeting that we decided that we did need to add the distance thing in here and that we were going to keep it.

DR. HENDRICK: Okay. Now, this is, again, a physicist performance test under the current ACR situations or you could do a focal spot size measurement.

In the QC tests that are in the final rules, is this also in there?

MS. BUTLER: The line-pair resolution is in there.

DR. HENDRICK: It is in there as 11 and 13?

TC:

MS. BUTLER: Yes.

DR. KOPANS: Barbara was just pointing out to me, is there a problem with this? You say the focal spot shall be such that with the film screen combination "using the facility, the system shall provide." Does that mean if you then go to a digital detector that has lower line-pair resolution capability, you can't use a different focal spot? In other words, you would have to still stick with the one that was capable with high resolution with film?

DR. HENDRICK: I think this isn't relevant to digital.

DR. KOPANS: Is that clear, though? In other words, I could envision this as being the X-ray tube that I

am going to use, if I put a film screen detector under it, it has to be capable of doing this. Whereas, if I am using a digital detector, a lot of the digital detectors may be add-ons.

DR. HENDRICK: Yes, I understand your interpretation. That may be the right one.

DR. KOPANS: I think that is the intent, though.

DR. HENDRICK: Yes, I think that is the intent. It is a test on is your focal spot too big or not, basically, the way it is written here.

DR. KOPANS: Right, but if you had a digital detector that had 5 line-pair per millimeter capability, then it would be better to work with a focal spot that was matched to that as opposed to maybe a lower output system that was small enough to meet this requirement. Do you see what I am saying?

DR. HENDRICK: Yes, I see what you are saying. It could impose constraints on digital that you may or may not want there.

DR. KOPANS: Variance, again?

DR. HENDRICK: No. I don't know that this is terrible.

Even if you use a digital image receptor, you still don't want the dominant loss of spatial resolution to

come from the focal spot. So I don't know that it is really out of line here, but when it is applied to film screen systems, it is a test of the whole system performance. When applied to digital, it is a test of the focal spot.

Joel?

DR. GRAY: Dan, one of the reasons that I have seen in the digital systems that I am talking about, CR and not in mammography, one of the reasons that they are performing as well as they do, even though they exhibit less resolution in screen-film, is that they have higher modulation at the low frequencies, and by doing this, by requiring higher resolution, if you will, from the focal spot, you are assuring that you have more modulation at those low frequencies.

So I think there is a distinct advantage in this. Now, whether the wording here would be directly applicable, I don't know.

DR. HENDRICK: Penny?

MS. BUTLER: One of the things we discussed during the QC section was the one that you just mentioned that the resolution tests the entire system, including the film screen combination, as you do this test.

I am wondering if, perhaps, we should include something about meeting NEMA focal spot performance

standards in this section as an alternative in case the film screen test shows that you are not meeting the 13 and 11. The reason I am bringing this up is, currently, in the ACR manual, basically, if you don't meet the 13 and 11, you should test using a slit camera and see if you meet the NEMA specs.

DR. HENDRICK: Yes. This, again, gets messy because we have got it in the QC part of the regulations already. The question is do we also need it in this equipment performance part of the regulations separately, and then, if we have it here, do we need to specify if this fails, go on and do this further test, which is a further QC test.

MS. BUTLER: No. Currently, the way it is written in the QC, the way we left it yesterday in the QC section was that this is a system resolution test, and basically, if you don't meet the 13 and 11, you have to find out what is causing that and sort between focal spot versus image receptor or anything else you have got there, although it wasn't written that way. I think it will come out in guidance, but it wasn't written that way in the regulations.

DR. GRAY: Yes. In the QC section, it is referred to as system resolution.

MS. BUTLER: As it is here.

DR. GRAY: Oh, is this here, too?

DR. HENDRICK: Yes, which is correct if you are talking about film screen.

DR. GRAY: Right.

MS. BUTLER: But if you are talking about the manufacturer complying with this, basically, they are stuck with their geometry and their focal spot, trying to make sure they comply with this based on those parameters rather than the image receptor.

DR. HENDRICK: Yes. So do we think it should be left in here as a system performance and equipment performance criterion?

MS. BUTLER: I would recommend taking it out and just leaving it in the QC section.

DR. HENDRICK: That is fine.

DR. GRAY: Does that create a problem, though? If it is in the QC section, that doesn't say that the equipment must meet this criteria when it is installed and delivered.

DR. HENDRICK: That is true, but this doesn't really say that either. I mean, this is still a facility requirement. It is not a manufacturer's requirement.

DR. GRAY: Well, then we don't need it here.

DR. HENDRICK: That is what Penny is saying.

So at least this side of the room thinks we should delete it here and leave it as a QC test on system resolution. Any disagreement?

Rita?

MS. HEINLEIN: No. I just think it has to be somewhere.

DR. HENDRICK: Okay.

MS. HEINLEIN: So I don't have a problem with moving it to QC.

DR. HENDRICK: Okay. What about (ii), for systems providing magnification, a focal spot that meets the following requirement shall be provided? This is specifying that you have to get at least this 11 and 13 in magnification mode, as well as contact mode, which a lot of current systems don't meet, by the way.

Yes. Dan?

DR. KOPANS: Isn't that the point I was making earlier that, in fact, with the contact mammography, the resolution is actually very similar, if not the same, to magnification? You are actually codifying that, saying it only has to be the same, and then the only difference would be noise, right?

DR. HENDRICK: No. You are saying that you can't use -- and actually, what needs to be added here is that

this should be tested under clinically relevant conditions. What you are saying is, when you go to magnification mode, you shouldn't resolve less in the plane of the breast. .5 centimeters above the breast support surface.

DR. KOPANS: But if you are going to require magnification, and most of the radiologists agree you should require magnification, it would seem to me that magnification should have to give you better resolution than the contact imaging capability. Otherwise, why require it?

DR. HENDRICK: Because the truth is that what you gain from magnification is blowing up the size of whatever you are looking at, microcalcifications or speculated edges, relative to the noise pattern in the film.

DR. KOPANS: Yes, which is what I was saying earlier.

DR. HENDRICK: Right.

DR. KOPANS: It is the noise benefit that you are getting.

DR. HENDRICK: Right.

DR. KOPANS: So you don't want to require higher resolution?

DR. HENDRICK: I think there should be some requirement. I just don't know that this is correct because, when I do these measurements, I find it improves in

one direction and degrades in the other direction. It is very hard to meet 11 and 13 with magnification as used clinically, even with the minimum available magnification factor.

Penny?

MS. BUTLER: I found the same things in my testing in some units. So I am really at a loss on what recommendation to make right now because, basically, I have no data to suggest what it should be under magnification, but I have a feeling that 13 and 11 is maybe a little bit too stringent.

DR. HENDRICK: Joel, do you have any comments or opinions?

DR. GRAY: No.

DR. HENDRICK: Okay. We have two choices. It sounds like we can leave it as it is here. We have taken out (i). Do we want to remove (ii) to a QC test requirement that if they have magnification, it should be tested and meet some standard, or do we want to take this out completely or leave it in here as it is?

Penny.

MS. BUTLER: I think the backup, particularly regarding the small focal spot is to go back to the NEMA

standards, if it doesn't meet the 13 and 11. Maybe we should consider adding this into the QC section.

DR. HENDRICK: I would agree that if we are taking (i) out for contact mammography and putting that in the QC section, this second part, if it goes anywhere, should probably be in the QC section. I think it is still open what exactly should be in there, though.

Maybe your suggestion that if you try the line-pair resolution, if that fails in magnification to meet these criteria, then you go back to focal spot measurement using the slit.

Rita?

MS. HEINLEIN: Ed, what did the comments say for this section?

DR. HENDRICK: (8)(ii), there are just a few comments.

MS. HEINLEIN: So do you get the impression from the fewer comments that most of the people that read that accepted the way this was written?

DR. HENDRICK: Let me just review them real quickly here. Yes. There were comments like the magnification should be taken at clinical geometry, which is, I think, a correct suggestion; that you shouldn't test the unit at a specified geometry if it differs from what is

done clinically. There were several comments to that effect.

Do you have your book? They are on page 180 and 181.

MS. HEINLEIN: Right.

DR. HENDRICK: Those were the only comments that I thought were really useful in this. We are saying do it at a clinical geometry.

Yes. Joel?

DR. GRAY: I would suggest that we delete this section. At the present time, there doesn't seem to be enough understanding among the committee members as to what numbers we should be using or if this is an effective test. So, based on that, I would recommend deletion.

DR. HENDRICK: Rita?

MS. HEINLEIN: Then, is there somewhere in the regulation that talks about resolution performance and effective focal spot? I mean, wasn't that the whole purpose here when we had this discussion initially, was to take it away from specifying what a focal spot size should be and, instead, tie it altogether and say this is what the system should be capable of resolving?

DR. GRAY: That is correct, Rita, but the point I am making is we don't know what numbers to put down here.

Therefore, we are regulating something incorrectly without any scientific data.

MS. HEINLEIN: I appreciate that. I guess the question then becomes do we need to have something in here that has anything at all to do with resolution or focal spot size or if it is stated that it is a specific focal spot size that it shouldn't be any larger or smaller than a certain percentage, or is that just covered under NEMA?

DR. GRAY: Yes. NEMA standards still apply, but that simply requires the focal spot size to be within a certain factor of the stated small and large focal spot sizes.

What I would suggest is moving this magnification test to the QC part, requiring the physicists to test in the clinical magnification setup, and find out what the spatial resolution is, not necessarily setting 11 and 13 as the requirements.

MS. HEINLEIN: Wasn't the purpose that on magnification, you should have at least the same, at a minimum, the same resolution that you would get on contact mammography?

DR. HENDRICK: That was the original thinking, but it turns out that is not always the situation, even though the image quality has improved for other reasons. You are

magnifying the object relative to the grain size and noise size on the film.

Dan?

DR. KOPANS: Just to answer what Rita is saying, I certainly would love to see specifications, but I would agree with Joel and Ed that one of the things we have learned -- and I think most radiologists haven't had their resolution checked in an objective way with magnification -- the spatial resolution, we have, I think, four different manufacturer systems. I think only one of them is actually 11 and 13 at mag, and the others aren't.

The image quality is improved because there is noise reduction, but the spatial resolution is actually equivalent or less. I don't know that there are many manufacturers that can actually meet this now.

DR. HENDRICK: Do any manufacturers want to comment?

Except John -- no, go ahead, John.

[Laughter.]

MR. SANDRIK: John Sandrik, GE Medical Systems.

I would certainly agree that, in general, particularly if you do not specify any particular geometry, I could pretty well say you will not meet these resolution requirements for any arbitrary geometry.

I think in some geometries, we can. If you go particularly to the maximum magnifications available, you are kind of at the border line and, in some cases, under that border line of what these focal spots will provide in resolution.

I think it has been pointed out several times the advantages enlarging the image, improving signal-to-noise ratio, but you are not going to see the resolution in general under any arbitration condition.

DR. HENDRI CK: So do we agree to move this to a QC test and not necessarily to specify a limit at this point until we know a little more for mag?

[Affirmative responses.]

DR. HENDRICK: Joe.

DR. GRAY: In items (B) and (C) under that, we recommended deleting previously.

DR. HENDRICK: Okay. Can we move on to (9), focal spot selection? "When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected. Then, the recommendation of some of the comments was -- and I think we recommended this as well the last time -- between (ii) and (iii) to put an "or." So it reads, "When more than one target material is provided, the system shall indicate, prior to exposure, the preselected

target material, or when the target material is selected by the system algorithm based on the exposure or a test exposure, the system shall display the target material selected after the exposure." So one applies to preselection; the other two, automated selection. You can't do both necessarily. Is that okay?

"(iv) When the selected target is related to the kVp, the system shall prevent exposure unless the correct combination of target and kVp is selected."

There were some questions, including my own, and comments about whether this was really needed.

Did we have a recommendation on this last time, Joel?

DR. GRAY: We had a modification the last time, but I am not sure what we recommended for modification.

DR. HENDRICK: Rita?

MS. BUTLER: I think one of the reasons this was discussed initially is that there are -- well, I am not sure how many, but there is some older equipment out there that will allow you to go to a higher kV, and then you have to automatically select the different filter necessary for that kVp. I think that is why this was discussed originally.

DR. HENDRICK: Yes, Charlie.

MR. SHOWALTER: My notes from April, what I have in terms of (9)(iv) was to delete the first portion of the sentence up to the comma, "When the selected target is related to the kVp," and the rest, just to continue with that.

DR. HENDRICK: The comments express some confusion as to what is meant as stated here. So I think that would clarify it.

Can we move on, then? Is everyone happy with th way we decided to handle it the last time?

(10) Focal spot location. This prescribes: "The focal spot shall be located so that the ray falling on the mid-point of the chest wall edge of the image receptor is within plus or minus 5 degrees of perpendicular to the image receptor." What did we do the last time.

DR. GRAY: We recommended deletion of item (10) the last time.

DR. HENDRICK: Okay.

DR. PATTERSON: And the comments this time were also in favor of deleting it?

DR. HENDRICK: There were comments to the effect that it would be difficult to measure in the field. One comment suggested the medical physicist should not be

required to measure this. I assume they wanted the State people to measure it.

Yes, there were a lot of objections to this, a reasonable number of comments pointing to the lack of clarity, the difficulty in measuring it in the field.

So are we happy in deleting it, leaving it deleted?

[Affirmative responses.]

DR. HENDRICK: Okay. For both (i) and (ii).

"(11) Filtration. (i) General. Each system shall comply with the beam quality requirements of 1020.30(m)(1) of this chapter for the minimum half-value layer...." There were some comments to the effect that this should be restated not in terms of beam quality, but as half-value layer. I thought those were good, that comment.

It gave specific language that this should be restated as a requirement on half-value layer and should read, "The half-value layer for the kVp setting for a 4.5-centimeter breast should be measured using 99.97 percent pure aluminium and shall comply with the beam quality requirements of 1020.30."

Independent of what you use as the material, do you agree with restating this as a half-value layer requirement rather than a filtration requirement?

Penny?

Cass says yes.

MS. BUTLER: I also agree, but again , I am wondering since this is covered in the QC section, we can manipulate it here, but should we move it to the QC section?

DR. HENDRICK: Yes. It is already covered in the Federal manufacturer requirements. It is covered as a QC measurement. Should we delete it here?

MS. BUTLER: It seems to be the direction that we are moving in.

DR. HENDRICK: Yes, it does. Okay. So we would remove it here, then, and it would be in QC. So we would have to move it as a QC requirement.

Some of the comments men tioned this, this provides a lower bound on half-value layer. It does not recommend anything about an upper bound.

Penny?

MS. BUTLER: We discussed in the QC section that we should include the upper level.

DR. HENDRICK: Okay, so you have covered that.

MS. BUTLER: But, Charlie, you raised a question on that. Could you restate that? Do you remember?

MR. SHOWALTER: Well, I think the only thing I said was -- I don't know what I said, but what I will say

now is that, obviously, there are arguments for and including an upper bound on the half-value layer; that there are other parameters in play that tend to keep the half-value layer from getting too higher, and we were not persuaded when we wrote the proposal that it was necessary to have an upper bound as a Federal regulation.

While everyone understands it is a good idea not to have a half-value layer that is too high, we were not persuaded that that should be a Federal requirement. If the committee wants to advise us that they think that should be a Federal requirement, we are ready to hear that, but we did not believe that when we wrote the proposal.

DR. HENDRICK: Elizabeth?

DR. PATTERSON: Looking at the minutes from the April meeting, the committee did agree to add an upper limit to that.

DR. HENDRICK: Okay. The only situations that I found are that there are some old glass-windowed X-ray tubes that had been used for mammography that gave very high half-value layers, whether you used filtration or not. They were filtering the beam quite heavily and, as a result, had pretty low output.

I haven't seen any of those in several years. So I don't know if anyone else has practical experience on this or not.

DR. GRAY: Was that dedicated equipment?

DR. HENDRICK: It was dedicated mammography equipment. It was just a glass-windowed tube.

DR. GRAY: A long time ago.

DR. HENDRICK: Yes.

Okay. I don't hear any strong feelings about having an upper limit. So this would, then, get removed, and it would fall back on a manufacturer's requirement and as a QC test. With a lower bound only, is that what I am hearing for the QC test?

[Affirmative responses.]

DR. HENDRICK: Okay. We would also, then, remove (ii) for variable filtration, parts (A) and (B). Is that correct? (A), (B), and (C)?

MS. BUTLER: No. This doesn't appear to be really a QC thing. It is not a test. It is sort of a design thing.

DR. HENDRICK: Yes, it is a design thing.

MS. BUTLER: So maybe it should be like a subsection of variable filtration with those specifications there.

DR. HENDRICK: I was just trying to see. It looks like the recommendation we made last time was to keep this, but to link (B) and (C) with an "or." I don't know that there is any point in having a different date for (C) than (B).

DR. GRAY: We deleted the date.

DR. HENDRICK: We deleted the date. Okay. So we would do that and keep it as a performance requirement?

Marsha.

MS. OAKLEY: What are you finally going to do? I'm sorry. I missed it.

DR. HENDRICK: The proposal is for (i), to move that to a QC test and remove it for (ii), variable filtration, to keep that as an equipment specification. Did we delete the effective date on (A) or keep that as 5 years out? I think we kept that.

DR. GRAY: The last time, yes.

DR. HENDRICK: Then (B) and (C) would be whenever these regulations go into effect. They would apply with an "or" in between them.

MS. McBURNEY: Does that mean for all equipment?

DR. HENDRICK: For all equipment, at least (B) and (C) apply to all equipment immediately when these regs go into effect. (A) would be 5 years later. If you want to

discuss whether (A) should apply just to newly acquired equipment, that is fine. Is that what you are proposing, Ruth?

MS. McBURNEY: I don't have a feel for it one way or another on that particular one.

DR. HENDRICK: I don't have a strong feeling.

MS. McBURNEY: If it is retrofittable for existing equipment.

DR. HENDRICK: I don't know of any equipment that has variable filtration type or thickness that doesn't have this kind of interlock, do you?

MS. BUTLER: I would like to hear from the manufacturers if one does, but most of the filtration units are relatively new units. I see a "no" back there.

DR. HENDRICK: You don't have any problems? Okay. So why don't we keep this as is.

I am going to stop here and turn it over to Joel since we are down to (12). Did you want to take a break at this point?

DR. PATTERSON: Yes. I think we will take the break at this time, and we will reconvene. Let's do a 10-minute break.

I have one question, though, for the presenters. Is there anyone who is planning on using slides at all?

Overheads, okay. Slides? Anyone planning on using the slides?

[No response.]

DR. PATTERSON: Thank you.

Will you remove those during the break, so we don't have to look around? Thank you.

Ten minutes.

[Break.]

DR. PATTERSON: Before we reconvene, I would like to bring us up to date again or reemphasize just what today is supposed to be doing.

Back in April, the committee gave their recommendations to the FDA on what we thought should be there or shouldn't be there or how to change it, et cetera. This session this time, we are supposed to be looking at the public comments regarding these and then our comments or recommendations regarding those public comments. Let's not rehash what we did in April, if possible.

All right, you are on.

DR. GRAY: I am picking up where Ed left off, page 14917, item (12), dealing with compression. I have tried to summarize on the overhead some of the comments in general, but I will go through each of these section by section if there is any comments in particular.

[Overhead.]

DR. GRAY: Compression, we are looking at actually four or five different aspects of it, the application, decompression, paddle, paddle alignment, and this alignment, there is some confusion here. Some of the alignment issues, we are dealing with the parallel characteristics as well as the edge of the alignment of the front edge of the paddle with the image receptor and the thickness display.

The numbers, by the way, on the right in parentheses are the number of comments received or roughly the number of comments saying something to that effect. Power compression, yes. It is a must. We should have it soon. About 30 people made a comment to this effect.

One comment is that the foot control is specified as too restrictive. This individual is looking more towards the future when apparently somebody has something in the back of their mind that might do the same job without the foot control. I am not sure what this is, but it was just a statement that it was too restrictive.

Interestingly enough, three people said that the fine adjustment was a costly burden that provided no benefit. I don't think Rita would agree with that, especially from the look on her face.

[Laughter.]

DR. GRAY: Power and manual adjustment is a must, must have both. It allows the technologist to use both hands. Four people commented to that effect, and I think most people would agree that that really is the intention, so you can use both hands for positioning.

Not necessary to have the fine adjustment powered was interesting. What do you think on that, Rita? I got Rita with some hard candy in her mouth.

MS. HEINLEIN: Yes.

[Laughter.]

MS. HEINLEIN: Not necessary to have the fine adjustment powered. I don't know that it is necessary that it be powered. I think that, again, if it is powered, it just gives them the advantage of keeping both hands on the patient while you are making those fine adjustments. Is it absolutely required? I mean, you could do it manually, but you still, then, have to take a hand off of that breast in order to do it manually.

DR. GRAY: Right.

There was some feeling, I think, that -- no pun intended when I said "some feeling" -- that the technologist should be doing it manually so they can actually feel, and they felt better adjustment was available manually.

MS. HEINLEIN: The only thing that determines when to stop compressing is the breast. So you need to have a hand on that breast. So I think the feel of the knob doesn't tell you anything. It is the feel of the breast that tells you. So you need that hand available.

MS. KAUFMAN: I was going to say that the fine adjustment has to be automatic.

DR. GRAY: I didn't go back and check that.

MS. HEINLEIN: I don't think it does say that.

MS. KAUFMAN: No. I don't understand the comment.

DR. GRAY: Okay. Well, maybe that was just a misunderstanding in the comment.

DR. HENDRICK: It just says it has to be operable from both sides of the examinee.

DR. GRAY: Okay.

MS. KAUFMAN: Yes, right.

DR. GRAY: Okay. So we will disregard that.

One manufacturer said that their system goes up to 17 pounds now. To upgrade it to 25 pounds would be impossible and costly, and they have about 2,000 units in the field.

Another individual said -- actually, I believe there were two or three individuals who said that 25 to 40 pounds would result in injury to the patient.

Rita?

MS. HEINLEIN: I have a question about the 17 pounds now and that to upgrade would be impossible. Isn't it currently required under accreditation that the unit under power compression meet 25 to 40 pounds? I mean, that is currently, right now, under ACR accreditation. Is that correct?

DR. HENDRICK: Yes. That is a QC test, but the way this one manufacturer has escaped it is to call what they do some kind of automated precompression and not compression, not the final compression which would be done manually.

MS. HEINLEIN: So it is a matter of semantics. They are calling it precompression as opposed to automatic compression. Aside from these regulations, I am just wondering that these 2,000 units right now, I guess, are --

DR. HENDRICK: I think it is a problem for these units right now --

MS. HEINLEIN: Right.

DR. HENDRICK: -- because the people who use them want them to go to higher compression forces so that they can be effective in mobilizing the breast with automated compression, and the manufacturer doesn't want to do that because they are afraid it will burn out their motors.

MS. HEINLEIN: It is a problem. I mean, I have worked with those units, and you are right. That 17 pounds is not sufficient compression to mobilize the breast. You wind up then having to take a hand away. It has the potential for compromising positioning.

DR. GRAY: (12)(i), that is basically a discussion about the power compression. The compression device shall provide maximum compression and all those issues. Are there any other points of discussion regarding the application?

Penny?

MS. BUTLER: I just wanted to point out in the ERG report on cost analysis that there was one manufacturer that said they were unable to retrofit to comply with item (C) which is the total pressure, and the cost of replacement would be $70,000. So you would have to replace the unit in order to fix it.

DR. GRAY: The sense I am getting is people think that is important, though.

MS. HEINLEIN: I think it is real important.

I was at a facility that had failed accreditation, and they deserved to. The sole reason was poor image quality due to blur and lost of breast tissue centered solely around the equipment's inability to provide proper

compression. Even at maximum using their hand, they couldn't get maximum compression.

DR. GRAY: Dan?

DR. KOPANS: I think I would certainly support the requirement for a minimum/maximum. I am just curious about the other end, limiting it to 45 pounds. What are the data for that? It really is pounds per square inch that is the major issue, and of course, that varies with the breast size and the elasticity.

Just to add a little question, the upper limit of 45 pounds, does anyone know where that comes from?

DR. GRAY: It comes from 200 Newtons.

[Laughter.]

DR. KOPANS: Thank you. I happen to come from Newton, and I happen to know that is not where it comes from.

DR. HENDRICK: I think it comes from the ACR QC manuals, and it was somewhat arbitrary. There is a paper by Dan Sullivan on response to different compression forces.

DR. KOPANS: But that turned out to be pounds per square inch, wasn't it, in terms of the larger breast instead of smaller and so on?

DR. HENDRICK: There is also something in there about just absolute compression force, not per square inch,

but I agree with your comments that, on the other hand, you don't want this to have no maximum at all.

DR. KOPANS: Just to emphasize what Rita said, with a very large breast, the upper maximum wasn't sufficient to keep it from slipping in the unit. So I am not sure I would change it, but I don't know what the science is to make 45 the upper limit.

DR. GRAY: Rita?

MS. HEINLEIN: As it is currently in the regulation, this maximum of 25 to 45 pounds, as it is in the regulation, would not go into effect until 5 years after this was enacted.

DR. GRAY: According to my notes, we struck effective October 1, 2000 at the last time we discussed this.

Is that correct, Charlie?

DR. FINDER: Yes.

DR. GRAY: Okay.

MS. HEINLEIN: I mean, I think it is very, very important for the overall quality of mammography.

Now, it may be that if there are 2,000 units out in the field that are going to cost $70,000 each to make that change, then maybe it does have to be pushed back 5 years, and that would perhaps give facilities enough time to

get ready to make that change, and I have no problems with that, particularly because of the numbers, but I think it is vitally important.

DR. GRAY: Do we want this to apply to present equipment or to equipment purchased after the effective date of the rules?

MS. KAUFMAN: Pres ent, but 5 years out.

DR. GRAY: Present, but 5 years out.

Do I hear 10 years?

MS. HEINLEIN: No.

I mean, the only reason I would agree to the 5 years out is because of the potential financial impact, and I am assuming these numbers are accurate, of 2,000 units at $70,000 or however, even if it was $60,000 each, and I think that would be something that I suppose the FDA has to weigh the financial impact of that.

So, in that regard, I would have no problems moving it 5 years out. I would certainly prefer to see it go into effect immediately, but when you weigh the financial impact, I can appreciate where you might be coming from.

DR. GRAY: Cass?

MS. KAUFMAN: I don't know. Is 17 pounds a sufficient amount of compression? Currently, I don't know

the answer to that. If it is, then that is fine. If it isn't, then they have got to bite the bullet.

DR. GRAY: Esther?

MS. SCIAMMARELLA: My concern is for the consumer perspective. They don't know. They go to a facility, and if they are missing anything, I think it is very serious, the compression issue.

MS. HEINLEIN: I agree. I think the compression issue is very serious.

MS. SCIAMMARELLA: How would you balance the concern of the consumer between cost?

MS. HEINLEIN: You can. It is much more difficult for the technologist, but with a good quality technologist, they know how to create eight hands out of the two hands that they have. In order to manually compress, it is just to make sure that there is sufficient manual compression available to maintain the breast in position.

MS. SCIAMMARELLA: There are two issues, but my concern is that some consumers have problems with the pain they suffer and they don't want to come back. There are a lot of things on that issue because the equipment is not too good, and I debate about that, too.

DR. GRAY: Let me clarify here. I think what we are talking about is 17 pounds under power compression, but

these units will still do higher than that manually; is that correct? So we can still get the compression manually. It is just not available with the power compression.

Dan?

DR. KOPANS: That clarified something for me, but we have done some preliminary work on variable compression, the issue of discomfort for the patient and so on. It is impressive to me how the last bit of compression really sharpens up an image in terms of moving the object closer to the film, spreading the structures apart.

I think 25 is probably a good level to shoot for, and I would agree with Rita. I think compression is very important.

I think what you want to do is have sufficient capability in the system to do what the technologist needs to do to get the best image. I have little doubt that there are breasts that are slipping if you can only get the 17 pounds. I don't have the science for that. That is anecdotal.

DR. GRAY: Charlie?

DR. FINDER: I just want to correct something I said. When I said about immediately, I was talking about (12)(i). For (12)(C), it was, at least from the last

meeting, for the year 2000. That is when it was recommended. I just wanted to clear that up.

DR. GRAY: So (12)(i)(A) and (B) would be immediate, and (C) would be the year 2000 or 5 years?

DR. FINDER: That is what was recommended in the April meeting.

DR. GRAY: Okay. Does anybody have an objection to that? Especially bearing in mind that we have powered compression to 17 pounds. We have greater than that manually now.

MS. KAUFMAN: How much compression do you normally use now routinely? I don't know the answer to that.

MS. HEINLEIN: I don't know that I know the answer to that. I mean, there are some units that give you a readout.

DR. HENDRICK: We have data on that. You very seldom max out the compression, but you operate in a range. Unfortunately, this is all in decaNewtons.

MS. HEINLEIN: Right.

DR. HENDRICK: I will give you the data.

MS. KAUFMAN: Is that 2000? I mean, I don't know.

DR. HENDRICK: Probably not. The question isn't what you compress to ultimately. It is does 17 pounds or

whatever you said was your minimum automatic compression for us to mobilize the breast in pretty much all women.

I also know anecdotally that some units that the manufacturer is saying can't achieve more than 17 pounds because of the way they have set up their powered compression have been changed to go to the 25 pounds, and they haven't burned out their motors like the manufacturer claimed they would do.

So that is not on all 2,000 units. That is on some of the units. It seems to be achievable. It is more protection for the manufacturer and service of that equipment than a real limit, it appears.

DR. GRAY: So can we recommend to the FDA that items (i)(A) and (B) be effective immediately, and (C), 5 years after?

MS. WILCOX-BUCHALLA: Pam Wilcox-Buchalla, ACR.

I just have a point of clarification. When you say immediate, does that mean from the date of publication which is proposed to be October or a year from then?

DR. PATTERSON: When they go into effect a year after the date of publication.

MS. WILCOX-BUCHALLA: So, if you were to change this to immediate, it would be 2,000 units that had one year to be replaced.

MS. KAUFMAN: If finalized.

MS. WILCOX-BUCHALLA: But they are saying it is going to be finalized October 1 of this year.

MS. KAUFMAN: Then they have one year after that.

MS. WILCOX-BUCHALLA: Right. So that is less than 2 years. Plus, nobody is going to know that until they come out in October.

MS. HEINLEIN: But we are saying that that part of the 25 to 45 pounds would be 5 years out.

MS. WILCOX-BUCHA LLA: Okay. I just wanted to get clear what "immediate" meant because, when we talk about replacing a significant portion of the units, we need to think about whether that is actually possible for the vendors, let alone the cost of it.

MS. HEINLEIN: But we are not saying that.

MS. WILCOX-BUCHALLA: I know we are not for this, but just because it came up at this point, I just wanted to make sure that we were clear.

DR. GRAY: Carl?

DR. D'ORSI: This is nothing to do with regulations. I just have a request for the manufacturers that they have some kind of a standard pressure gage to measure this pressure, so that we know basically we can look around and see what type of compression we are getting.

I know some of the machines have them, but they vary in decaNewtons, Newtons, bars.

DR. GRAY: The ACR manual shows a photograph of a bathroom scale that costs about $15.

DR. D'ORSI: Yes, but it is really difficult to put a breast on a scale when you are compressing it.

[Laughter.]

MS. HEINLEIN: And some times those breasts weigh so much that you automatically get a higher pressure. Some of them just record F, 19F. I am sure the patient has a few ideas what F might be with that compression, but I guess it just means force, but that is all it said. So you are right. I think that is a really important point that they vary from unit to unit.

DR. GRAY: Does anybody have any problem with the way we proposed it? (i)(A) and (B) immediately, and (C), 5 years.

Cass?

MS. KAUFMAN: That is fine.

There was on e comment, though, that talked about maintaining the force for 15 seconds.

DR. GRAY: I have got that coming up here.

MS. KAUFMAN: Okay, thanks.

DR. GRAY: Okay. Item (ii), decompression, basically says that there has to be an override if you want to -- well, let me read it. It says, "If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of the power to the system, the system shall also provide an override capability to allow maintenance of compression and shall continuously display the override status."

There were a couple of comments on this, and one of them was, must the display of the override status work if the power fails. In other words, if there is an LED readout and you would want it to work in the case of a power failure, then you would have to have some type of battery backup.

Another individual said let's not be so specific and allow for other methods. In other words, reword this to emphasize outcomes. There were several comments in here saying that we would be better specifying outcomes.

Section (B) under that is, "Each system shall provide a manual emergency compression release that can be activated in the event of power or automatic release failure," and (C), "If the system is equipped with a remote compression release control for the operator, the release control shall be located in a position that allows the

operator to observe the examinee during activation of the release control."

Any comments about section (ii), de compression, now?

[No response.]

DR. GRAY: Okay, moving on. Section (iii), compression paddle, "Systems shall be equipped with different sized compression paddles that match the sizes of all full-sized image receptors provided. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for 'spot compression') may be provided," and I emphasize the word "may" there. "Such compression paddles for special purposes are not subject to the requirements of paragraphs...," specified here.

"When compression is applied, the compression paddle shall be flat and parallel...," let's hold that one for a second.

I am raising a question about why we are using the word "may" relative to spot compression devices. Let's see. Can we take a look at the next overhead, please? I thought there were some comments.

[Overhead.]

DR. GRAY: Yes. These are somewhat out of order. Required at the spot compression, be available at all facilities, and there were two people who made that comment. Was there some question that this is a "may"?

Dan?

DR. KOPANS: You don't need spot compression in a screening facility, for example.

DR. GRAY: Okay. Does that sound reasonable to everyone?

[Affirmative responses.]

DR. GRAY: Okay. Then, it will stand as it is.

Any other comments regarding (iii)(A)?

[No response.]

DR. GRAY: (B), "When compression is applied, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface...," et cetera. Then there is a testing procedure outlined there.

Could we go back to the previous overhead?

[Overhead.]

DR. GRAY: Apparently -- and I don't have it in my notes, but apparently, we agreed in the previous meeting to delete the section of paddle alignment. At least one person pointed that out. Also, delete the test method, physicists

can decide how to do that. Three people made that comment. One person indicated if we do this at maximum pressure that this could result in cracking, especially if you are using a small device in the interior of the compression paddle. Another individual said there is no scientific data to show that the paddle must remain parallel.

Next overhead.

[Overhead.]

DR. GRAY: Requirements are difficult to meet on a 24-by-30. Nonparallel may be beneficial, and I should point out that there are at least one or two vendors providing nonparallel compression paddles at this time.

Six people wanted to know what the test obj ect would be. Most of them objected to the hockey puck-type of device that was suggested, and one raised the question of how flat and how parallel.

I guess, to me, parallel means parallel. There is on deviation.

Dan?

DR. KOPANS: I have trouble with making this -- pardon the pun -- so rigid.

[Laughter.]

DR. KOPANS: I guess I sort of have a conflict of interest, although it is not a financial one, in that we

have developed a paddle that tilts to compress the front of the breast which with a parallel compression paddle doesn't get compressed in many individuals. That has already been shown in a study to improve image quality.

Again, I suppose it could be a variance, and I understand the intent of this was the old sort of floppy paddles that weren't really doing a good job of compression at all. You would like to avoid that, but I think it is too restrictive, and in fact, there is another system, the Sophie unit, where the compression comes down at the chest wall side, trapping the breast, which is an advantage, and then tilts down.

It says when compression is applied, the compression paddle shall be flat. That would not be allowed, and yet, I think there is an advantage to doing that, too.

So, somehow, this needs to be either reworded or eliminated because there are already improvements that would be, I think, violating this requirement.

DR. GRAY: Ed?

DR. HENDRICK: I can't think of any way to reword this so that it really does what we want it to do. So I guess I would suggest deleting it.

DR. GRAY: Penny?

MS. BUTLER: I concur.

DR. GRAY: Rita?

MS. HEINLEIN: Well, I think one of the problems with deleting it is that there are a number of equipment out there that have compression paddles that, when you compress the breast, they tilt up at the chest wall, and then you run the risk of losing tissue posterially.

Now, I have never done a study on that, Dan, to be able to give any kind of scientific data on that, but that was the reason behind it.

As far as Dan's comments, I have worked with the compression paddle that you can adjust anterially to compress the front of the breast, and I think it is outstanding. I think having the opportunity to work with it, I wish every piece of equipment offered it because I think it is really wonderful, although I have had the chance to work with the other unit and I don't know that it is as wonderful.

So I think it is tough. I think what we want to try to do is to make sure that the equipment that is not designed to have a compression paddle that will move, that the compression paddle will not move. I don't know how to do it.

MS. WILCOX-BUCHALLA: Pam Wilcox-Buchalla.

Rita, I think what we would see is, on the clinical images, they are not going to pass if they have got a floppy paddle. I see it all the time. So would it not be appropriate, perhaps, to move this to guidance as opposed to a reg and then be able to address these newer technologies that are coming along so that we don't eliminate good equipment?

DR. KOPANS: I am trying to think of a compromise here. Despite what I think is a better paddle, I think Rita's point is well taken, and maybe Pam's solution is the way to do it.

Perhaps, if somehow you wrote in -- and I don't know the exact verbiage -- if, by design, the paddle is not intended to improve image quality by tilting, it should be parallel or something like that. Too complicated?

MS. SCIAMMARELLA: You clarified the existing new equipment, but you include for the ones they don't have. I think that would be a good idea.

DR. HENDRICK: Yes. I would just suggest that you imagine inspection procedures under the final rules if you leave any semblance of this in there. Your MQSA inspector is going to come in and do some test like this. It may not be exactly this one, and I would say quite a number of sites tell you that your paddles aren't parallel.

MS. KAUFMAN: Again, I think we shouldn't design regulations around inspections.

I don't know what the proposed inspection procedure would be like, but I suspect that it would not include this test. We currently have lots of tests that the physicist is required to do that we don't do during inspections, and I would anticipate that this would probably be one of those tests, if we need it.

I rather like Dan's idea about saying if it is designed to be parallel, it needs to be parallel, and if it is not, it doesn't.

I am a little bit concerned about waiting for accreditation because they only see those films once every 3 years, and they pick their very best film. So you might not see the larger breasts, and that is kind of after the fact because, then, they have been doing it for 3 years or something like that. So I am a little bit nervous about leaving it up to the clinical image review process to find it.

DR. GRAY: Penny?

MS. BUTLER: I like the idea of putting it into guidance, in effect. There is already guidance out there, the CDC ACR document for new equipment and also the ACR manuals as far as performance goes.

DR. GRAY: Rita?

MS. HEINLEIN: I support what Cass said and what Dan said. I think we should just say if it is supposed to be parallel, it should be parallel. If it is not designed that way, then it is okay.

To what you said, Ed, you are right because people may go in and test these paddles and find out they are not parallel. That is the whole purpose.

DR. HENDRICK: Nothing is going to be parallel, Rita.

MS. KAUFMAN: Well, it allows a 1-centimeter deflection.

DR. HENDRICK: Well, that is different from parallel. That is another issue. The word "parallel" has a specific meaning, and a 1-centimeter deflection is not parallel.

MS. KAUFMAN: Well, it shall not deflect from parallel by more than 1 centimeter.

DR. KOPANS: Just to add another problem here, because I am not sure how to resolve this, first of all, I would disagree. I think once you have something in regulation, inspectors will use it potentially inappropriately. We have seen that in the past, but the other point to be made is we have one system that is as

rigid as you could ever want, and the technologists find the patients hate it because it doesn't flex at all.

This is a tough regulation, and I would be very careful with it. I am a little schizophrenic, I think, in how I feel about it.

DR. GRAY: What shall we advise the FDA regarding (B)? Move it to guidance at this point? Does anybody object to that?

DR. HENDRICK: Well, I object to moving this test procedure to guidance because it is untested, as far as I know. Has anyone ever done this?

MS. KAUFMAN: It is my understanding that in al l of these tests that FDA got them from some source; that they weren't made up.

I thought it was something that the AAPM came up with.

DR. HENDRICK: Well, let me rephrase the question. Has anyone in this room done this? I hardly feel comfortable in acting on results that are unknown, unpublished, and haven't been tested out by somebody in this room.

DR. GRAY: We had one hand back there.

MR. SANDRIK: John Sandrik, GE Medical Systems.

At the risk of incurring some corporate wrath, I could at least tell you we have done the tests, and generally, the paddles will not pass this test.

DR. GRAY: I should point out a couple of comments, and maybe I didn't put them on the overheads. One was, since this thing is only a centimeter-and-a-half thick, one individual was concerned that some of these devices may not actually continue the compression down that low. Other individuals were concerned by putting a 12-centimeter-diameter device on a larger piece of thin plexiglass at 45 pounds, you may end up cracking it. So there are some concerns like that, and we don't have any answers to those at this point.

So I guess what I would try to suggest at this point is to move the first sentence of (B), which is just saying the thing should be parallel within a centimeter or so, perhaps moving that to guidance and deleting the compliance test that is specified here. How do people feel about that?

Penny?

MS. BUTLER: I agree.

DR. GRAY: Rita, agreed.

Ed?

DR. HENDRICK: Sure.

DR. GRAY: Okay. So that will be the recommendation. We will take the first sentence, move that to guidance, and delete the rest of (B).

Item (C), "The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor." It sounds like motherhood and apple pie and all of that? Any objections?

[No response.]

DR. GRAY: Okay. "The chest wall edge should be bent upward, forming a lip to allow the examinee comfort, but shall not interfere with the image at the chest wall." Okay.

Dan?

DR. KOPANS: Back to (C) for a second, "The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor." Again, the paddle that we have designed actually takes into account the fact that the axillary tail of the breast may be thicker and will tilt to accommodate that. Again, we can probably deal with that in variance. I don't know. We will deal with it in variance. I don't want to tie up this committee on one paddle design.

DR. GRAY: Rita?

MS. HEINLEIN: But, Dan, the edge of that paddle, when you just bring it down, it is straight.

DR. KOPANS: It is in the same plane, but again, an inspector could say it is not parallel.

DR. GRAY: Carl?

DR. D'ORSI: I just want to underscore what Dan said. We are thinking of another paddle design which wouldn't fit this straight edge, also, but again, we can deal with it in other ways. It is something to put in the back of your mind.

DR. KOPANS: How about "aligning" with the edge of the receptor? Take out the "parallel."

DR. GRAY: Well, first of all, there is the word "straight" here. You are talking about a device that is not straight.

DR. D'ORSI: Straight, correct.

DR. GRAY: You are straight or you are not straight?

[Laughter.]

DR. D'ORSI: I don't know. It has gone both ways, Joel.

I am speaking not about the parallel. I am speaking about the straight edge in the back.

DR. GRAY: And the one you are proposing would be or would not be?

DR. D'ORSI: Would not.

DR. GRAY: Would not be. So the word "straight" may be a problem, also.

DR. D'ORSI: Correct.

MS. HEINLEIN: I think that that should, then, go to variance. I mean, I think straight versus curved is important, and we have those old curved paddles. That has shown there was a loss of tissue. That is why they went to straight. I mean, this hasn't even been designed yet. I don't think we should make changes in that. Isn't that something, Carl, they could go for variance?

DR. D'ORSI: The edge, the back edge, not the surface of the paddle.

MS. HEINL EIN: Right, I know. That is what we are saying, yes, the back edge. It shouldn't be curved straight, and you are saying you are thinking about one that would not be.

DR. D'ORSI: Correct, yes. Let's get off of this. It is just to put an idea in the back of your head that there may be problems in the future. That is all.

DR. GRAY: Okay.

DR. KOPANS: What about changing it to "aligned," thought, rather than "parallel"?

DR. FINDER: If I could just make one comment.

DR. GRAY: Charlie?

DR. FINDER: We are now getting into really micromanaging the wording of this thing rather than the concepts, and what we need to discuss here is not whether you want to change one word or whatever, but whether these things are appropriate overall.

We are still on (12) here. So I think we are going to have to stick on the bigger issues.

DR. GRAY: Okay, move on.

Item (iv).

MS. KAUFMAN: On item (D), there was a comment that said that the use of "should" has little meaning and is unenforceable. If this item is important to quality mammography, then the requirement should be mandatory.

DR. GRAY: Okay. I think the Charlies can deal with that issue.

Item (iv), compression paddle alignment. Now, I had a note in here that this is to be rewritten and converted to simpler language. Is there any sense in spending any time on this at this point?

Penny?

MS. BUTLER: I just want to point out that in the QC section, we referred to the section, and actually, we should pull this out and stick it in the QC section in simpler language.

DR. HENDRICK: Yes, I agree with that.

DR. GRAY: Okay. So item (iv) should be removed to the QC section, and actually, originally, we suggested deleting section (D) of (iv).

MS. BUTLER: Joel?

DR. GRAY: Yes.

MS. BUTLER: Back on (A), also, the errors should be corrected in the revision, plus or minus.

DR. GRAY: Right, right.

Okay. Display of compressed breast thickness, item (v), previously, we suggested eliminating sections (A) and (B). So we are really only looking at that first paragraph that says, "Effective October 1, 2005, the compressed breast thickness shall be displayed invisible to the operator during positioning." That eliminates the compliance test and the tolerance of plus or minus a half-a-centimeter.

No comments?

DR. FINDER: What about the public comments? Were there any?

DR. GRAY: Yes. It should be deleted, the question of the test object, flexibility of the arm. These same issues keep coming up again throughout all of this; that the test object has not been tested, whatever.

Before we go on to item (13), the technique factors, there was a recommendation the last time we discussed this that there should be a minimum time specified that the compression device holds the compression in place. That was brought up by, I believe, only one person in the public comments, but I think it is an important issue that should be dealt with. Are there any questions regarding that?

MS. KAUFMAN: Where are we? On (13)?

DR. GRAY: No. We are still on (12). There is no comment in (12) about the compression device being able to hold the compression for any period of time.

Then we said we felt that it was essential that it holds it for some period of time, and I don't think anybody was willing to specify what that period of time was, but it should be something.

MS. KAUFMAN: The comment said 15 seconds.

DR. GRAY: The public comments, yes.

MS. HEINLEIN: Did you say there was one?

DR. GRAY: Yes.

MS. HEINLEIN: Okay.

DR. GRAY: Any other comments? Dan?

DR. KOPANS: I think it is a good public comment in that we have seen compression devices that you bring it down, it compresses, and then it starts losing compression while the tech is making the exposure.

I don't know what the appropriate time would be, but at least 5 seconds, I would think. Maybe 10 would be better because some exposures go fairly long.

DR. GRAY: Well, you would have to give time for the tech to get from in front of the patient to around the barriers. So you need some reasonable period of time.

DR. KOPANS: Any science on how long that takes?

DR. GRAY: We haven't done a study on that yet.

Item (13), technique selection and display. Here we go. There was a comment that this is already covered in 21 CFR 1020 and should apply only to manual mode. The question was what factors need to be preindicated.

There was sort of an implication in here that kVp and mAs should be preindicated, but it doesn't say that, but I think somebody was asking for that clarification. Really, the only thing you could preindicate is the kVp, and you can't even do that on some of the units.

There was one comment that AEC is costly, and somebody said most units may not have this feature, which I find surprising.

One of the issues that I would raise regarding the mAs readout, in particular, is that that is very valuable if you want to do patient dose survey as opposed to putting TLDs on the patient. You can have the technologist record the mAs and then go back and determine what the dose was to a large number of patients.

So, going through the section, at the present time, section (i) is selection of manual technique, mAs shall be available. All technique factors shall be clearly displayed at the control panel prior to exposure. When operating in AEC mode, the system shall indicate initial technique factors prior to exposure, and that is the one that at least one person was questioning.

Following AEC mode use, the system shall indicate the actual kVp and mAs used during the exposure. Actually, that is the comment about the AEC, as the mAs readout would be costly and most systems may not have this feature. I think quite a few of them do at this point. Some of the older units don't have it, but we have actually added it onto a couple of our older units, and it is relatively easy

to do with an in-house service engineer who is able to do it inexpensively.

Item (iv) under (13), all indications of kVp shall be within plus or minus 5 percent. We asked that that be deleted the last time. There is no need to specify the accuracy on that readout.

MS. BUTLER: Which one are you discussing?

DR. GRAY: Item (13)(v).

MS. BUTLER: Okay. Can we just discuss the things you outlined here first before we get into the stuff that is effective 5 years later?

DR. GRAY: Sure.

MS. BUTLER: I would like to point out that on (iv) where we talk about indication of actual kVp and mAs that one of the manufacturers responded that they didn't have a fix for this, and the fix would be replacing the unit.

DR. GRAY: Dan?

DR. KOPANS: I w ould just like to put in support for having this. As a radiologist, we use it all the time if there is something about the image that we are not happy with, to try and determine what actually the exposure values were, so we can decide whether it is just kVp or density as the systems talk about the mAs.

DR. GRAY: Yes.

Ruth?

MS. McBURNEY: If the allowance for plus or minus 5 percent is removed, what would indicate compliance, then? Would it have to be exact, then?

DR. GRAY: There would be no indicati on, no indication of accuracy.

MS. McBURNEY: So it would just have to be displayed.

DR. GRAY: To put a plus or minus 5 percent on a readout like that, I am not sure that is a reasonable requirement because, for the purpose it is being used for, the accuracy is not -- at 5 percent, you are talking about roughly 1 to 1.5 kV.

MS. McBURNEY: Right.

DR. HENDRICK: Isn't that a physics QC requirement, anyway, and that is why it was deleted here?

MS. McBURNEY: Oh, that is why it was promoted here.

DR. GRA Y: Are we talking about an indicator or a calibration?

DR. HENDRICK: We are talking about the indicated kVp --

MS. McBURNEY: Right.

DR. HENDRICK: -- agreeing with the measured kVp, which is what this would be tested by.

MS. McBURNEY: Right.

Is that already in the QC?

DR. HENDRICK: Yes.

MS. McBURNEY: Oh, okay.

DR. GRAY: Well, are we talking about it versus an indicated or versus a set? If I am going to make the test, I would do it versus what I set, not necessarily what the indicator said.

DR. HENDRICK: No, it is the same thing. I mean, you set it on the machine using the indicator on the machine.

MS. KAUFMAN: What it says under QC is that the kVp shall be accurate to within -- right now, it says plus or minus 10 percent, but I know we recommended 5 percent before.

DR. GRAY: Of the indicated, right.

MS. KAUFMAN: At the lowest and highest clinical values and at other commonly used clinical settings, the kVp shall be accurate. I mean, it has got to be the indicated. What else is there?

DR. GRAY: Well, in manual mode.

MS. KAUFMAN: It is still indicated.

DR. GRAY: Okay.

MS. KAUFMAN: And I might point out that there were four comments that agreed with the 5 percent accuracy. There was one that disagreed, and there was one that thought that the 5 percent was too lenient. So, overall, there seems to be a lot of support for requiring an accuracy of 5 percent.

DR. GRAY: Does anybody recall why we recommended deleting this the last time?

MS. BUTLER: Because it was in the QC sectio n.

DR. GRAY: Okay. So we could still recommend deleting it since it is in the QC section; is that correct?

MS. BUTLER: Yes.

DR. GRAY: Okay. Going on to item (vi).

MS. BUTLER: Wait a minute.

DR. GRAY: Penny?

MS. BUTLER: I am very concerned about those units which are out there that don't have mAs indicators, and the way this is currently written, if I am not incorrect, is that when this goes into effect, they have to have mAs indicators. I think we need to give them some time to buy new equipment.

There was another thing where we talked about it into effect for 5 years for the facility. I would like to recommend that it goes in place here.

I just don't think there is going to be enough time for a lot of facilities to go through the whole budget process to replace a unit.

DR. GRAY: What proportion of units or how many units don't have mAs indicators on them now?

DR. HENDRICK: I would guess about 20 percent, 20 or 30 percent, something like that.

DR. GRAY: All right.

MR. SHOWALTER: This was proposed as being most of these requirements or many of them going into effect 1 year after date of publication. That is also something that could be up for consideration. Is 1 year enough time? This has been brought up a couple of times. I know Pam brought it up in relation to one issue, and here it comes up again.

Is 1 year enough time to cushion the economic impact for some of these requirements, or would some longer time be appropriate for the general run of requirement? That is another issue.

DR. GRAY: I would raise the question in an opposite way. If these are needed for quality, can we wait more than a year?

MR. SHOWALTER: A fair question.

DR. GRAY: If there are specific ones like this, we could call this out and make this a 5-year or a 2-year or whatever.

Esther?

MS. SCIAMMARELLA: I think we need to be consistent with other guidelines. I mean, people need to update the equipment who are doing it because they want to perform better. I think 1 year after the regulations are in place is fine.

MS. KAUFMAN: I would never oppose the 1-year requirement, but I do think that it is mandatory that the u nit have AEC, but the post-exposure mAs readout, while a very nice feature, I am not sure that it would be mandatory for health and safety and image quality.

DR. GRAY: That is correct. It has nothing to do with image quality.

MS. KAUFMAN: Yes.

DR. HENDRICK: Well, it has something to do with image quality, but only if it gets tracked to the film that the radiologist looks at. Then it can be used to diagnose whether you have technique problems or not. If it doesn't get matched up with the film, it is only useful to see, like on mobile units, if your exposures are in the right ball

park before you take a bunch of films and don't process them immediately.

DR. GRAY: In order to move things along, does anybody have an objection to putting item (iv) at the 5-year level? That is the mAs readout for AEC mode.

[No response.

DR. GRAY: Okay, let's do that.

MS. HEINLEIN: Question, questio n.

DR. GRAY: Rita?

MS. HEINLEIN: Often, if the unit does not have an automatic kV, where the technologist selects the kV, often, they get into the routine of just setting one kV forever for everybody, regardless.

With an mAs readout at the end, that at least gives them the advantage of looking at the mAs to see if the mAs is down at 45. Then, they know if they are at 28 kV that they can quite comfortably drop down in kV and get a little bit better contrast.

The reverse is true. If they do everybody at 25, regardless of who they are doing, and they get a 320 mAs exposure, this is a clue that they can increase the kV and reduce the exposure time and reduce the potential for motion. That is one thing that I know the technologists use the mAs readout for.

Again, in agreeing with something you said earlier, Joel, how difficult is it to add an mAs readout meter to equipment?

DR. GRAY: I know on the units that we had, it was not difficult at all. I can't speak for vendors' equipment. Does anybody have an ID on that?

DR. HENDRICK: I don't know of any units where it is impossible to do that. I mean, Charlie mentioned one, but I thought it was a pretty easy retrofit.

MS. BUTLER: I would just like to point out that in this ERG report which was complied by submissions from manufacturers, there was a manufacturer that said that they couldn't do it and you had to replace the unit.

DR. GRAY: How many units did that manufacturer have out? Did it say?

MS. BUTLER: I don't have that information in front of me.

MS. HEINLEIN: I just see it as an advantage to have that mAs readout because it does help the technologist. It is like one more ump in making the decision to manipulate the kV.

DR. GRAY: Well, they don't have it now. Can we wait 5 years, considering the economic impact?

Dan?

DR. KOPANS: If we go back to health and safety, the issue of taking multiple films to get a better picture, we are just talking here -- many radiologists just tell the technologist to go in and get me a better image, sort of thing, which we don't condone, but if the technologist doesn't really know where she is operating, it is just sort of a shot in the dark and you end up exposing people to more radiation than they need.

I would be a little surprised. I mean, I don't know that much about electronics, but it seems to me it is just putting in a circuit to read a flow. I can't imagine that that company can't update their equipment.

I would say for this regulation to make it sooner rather than later.

DR. GRAY: Rita agr ees.

Elizabeth?

DR. PATTERSON: Joel, I would like to ask the manufacturers back there if it is possible to retrofit equipment with an mAs reader. I mean, my electrical knowledge, it seems like you ought to be able to plug here and here and have it going through a meter that is going to give me a readout.

MR. SANDRIK: John Sandrik, GE Medical Systems.

Our oldest systems do not have such a meter. We have an upgrade kit available to upgrade it. I don't know how difficult it is to actually do it, but the kit is available to do the upgrade.

We did not indicate having to replace the equipment for the mAs meter.

DR. PATTERSON: Do you know the approximate cost of the upgrade kit?

MR. SANDRIK: I imagine it is probably under $1,000, in the 500 kind of thing, something like that. I really don't know exactly the cost, but I think $500 to $1,000, kind of ball park.

DR. GRAY: Anybody else?

[No response.]

DR. GRAY: So I am hearing on my right, we should implement this as quickly as possible. Esther agrees. Cass. Ed doesn't disagree. Is that the same as agreeing?

DR. HENDRICK: Yes.

DR. GRAY: So that would be 1 year after.

Going on to item (vi), each system shall provide at a minimum for the selection of two potentials between 22 and 34 kV. Selection of kV shall be available in no greater than 1 kV steps.

Let's take that before we take the mAs issues. I don't recall if there were any major comments about the kV in the public comment section.

We will go on to (C).

MR. SANDRIK: John Sandrik, GE Medical Systems.

I would like to make one comment that, given the range required of 22 to 34 kVp, we find that range is inappropriate for using the rhodium track and in conflict with other requirements in the standard that requires appropriate combinations of kVp and track. We view this appropriate for moly and moly only. Thank you.

DR. GRAY: So should we clarify that and say for moly/moly, 22 to 34?

MS. KAUFMAN: There were two comments. They are just listed under the wrong thing in the book.

DR. GRAY: I thought I saw something in there.

MS. KAUFMAN: Yes.

One comment suggested that the specification be limited to moly/moly, which is what we were just talking about, since the range of 22 to 34 may not be correct for other target filter combinations.

The second question, the proposed requirement include 22 kV since the comments experience the lowest technique commonly used is 25 kV. The comment recognized

that the 22 might be a value in the case of specimen, but not from a safety aspect.

DR. GRAY: So, bottom line, we can let this stand if we add moly/moly to it? Any objections?

[No response.]

DR. GRAY: Okay.

MS. BUTLER: Joel?

DR. GRAY: Penny.

MS. BUTLER: I would like to recommend that this go into effect for new equipment purchased after rather than right now. Well, this is an effective 5 years from now.

DR. GRAY: No, that is 10 years.

MS. BUTLER: Ten years from now?

DR. GRAY: Yes.

MS. BUTLER: I would like to suggest that it go for new equipment, though.

DR. GRAY: New equipment only? So we would not have to retrofit, in other words?

MS. BUTLER: Right.

DR. GRAY: Is there any objection to that?

MS. KAUFMAN: I know there is one unit that only has 2 kVp increments, and I think that kind of stinks. There aren't very many of them. So I am not sure this is

going to have a big impact on facilities to put this requirement into effect.

DR. KOPANS: I support the 1 kV increment, but I think, Ed, you have done work looking at kV. I mean, 2 kV, I don't think a radiologist could tell the difference.

MS. KAUFMAN: No, but it may make a difference in dose.

DR. GRAY: Not significantly.

DR. HENDRICK: Yes, it will, but the question is how much do we want to prescribe this.

DR. GRAY: And the cost of this to the facilities to replace what they have now.

DR. HENDRICK: Yes.

DR. GRAY: Are the facilities that have these other units now producing poor-quality mammograms because of this?

MS. KAUFMAN: Yes. The ones we have seen have not been good facilities.

DR. GRAY: They are no t good facilities, but is the reason for it the equipment that doesn't have this capability?

MS. KAUFMAN: I think it is a number of factors, this being one of them, but also, I don't think there are

that many units out there that don't meet this. I think we are talking about a really small number.

DR. GRAY: Why don't we leave that with the FDA. They have heard our comments on it. They can decide how to handle it.

Adjacent mAs settings shall differ by no more than 26 percent of the lower of the adjacent settings. A combination of exposure time and tube current shall be available over a range of 5 to 300 mAs.

There were quite a few public comments on this. The 26 percent of the lower mAs would preclude low mAs needed for specimens. In other words, a lot of the devices now have steps of maybe 1, 1.5, 2, 2.5 mAs at the low end of the scale, and you need that for specimens. If you have got to go down to 26 percent, then the manufacturers would probably remove those low mAs settings from the systems.

One comment was made that only 4 percent of the exposures are made in manual mode; therefore, consider this particular section for deletion.

Another one said limit the settings to greater than 5 mAs, but it is my understanding that that would mean that you couldn't do specimens on it.

MS. KAUFMAN: No, no. The comment said limit the 26 percent requirement to those above 5 mAs.

DR. GRAY: Oh, is that the comment?

MS. KAUFMAN: Yes, and that really kind of makes a lot of sense.

DR. GRAY: The one other comment is, why specify a minimum mAs in the first place.

MS. KAUFMAN: The idea here is that you don't want to have your only option be, for example, 25 mAs and the next would be 50 mAs because, then, you may have to give the patient more radiation. Let's say they need 30 mAs. Then you would have no choice in terms of selecting the technique that you want.

DR. GRAY: But the issue is why set a minimum. Why do we want to say 5 is the minimum mAs? We may need 1 mAs or 2 mAs.

MS. KAUFMAN: No, no. Th at is not what they are recommending. They are recommending that the 26-percent difference only be applied to values higher than --

DR. GRAY: I am combining the question with why specify a minimum mAs in the first place. I am asking a different question, Cass.

MS. KAUFMAN: I know, but I don't think it does specify a minimum mAs.

DR. GRAY: The next section specifies a range of 5 to 300 mAs, and someone is raising the question as to why do you want to specify the minimum.

MS. KAUFMAN: I don't care about that.

DR. HENDRICK: And the answer is so you can so specimen radiography.

DR. GRAY: But perhaps you need less than 5 mAs.

DR. HENDRICK: No, you don't.

DR. GRAY: For conventional?

MS. KAUFMAN: For specimen, a lot of them are using cardboard. I mean, you are not concerned about dose.

MR. SHOWALTER: Just as a point of clarification, the manufacturer is free to go less than 5 if they so desire.

DR. GRAY: Okay. Let's go back to the 26 percent steps, then. Are people comfortable with that, a difference of 26 percent in mAs adjustment?

MS. KAUFMAN: I am comfortable if we put that comment in about that this applies for 5 mAs or higher, put some lower value in it, so that you don't have to have 26 percent between 1 and 2 mAs or whatever.

DR. HENDRICK: Or 10 mAs and higher, something like that.

DR. GRAY: Okay. Section (14), radiation output.

Penny?

MS. BUTLER: I would like to recommend that this entire section that we just discussed goes in for new equipment.

DR. GRAY: After 10 year s?

MS. BUTLER: I think we said 5 years, though. Isn't that what we are talking about?

MS. KAUFMAN: No. Right now, it is under 10 years.

MS. BUTLER: Right, but just lump it into the new equipment acquired.

DR. GRAY: After 5 years, after the regulations.

MS. BUTLER: After 5 years, yes, whatever the wording was.

DR. GRAY: Okay. So 5 years for (vi). Is that what we are talking about?

MS. BUTLER: Yes, that whole section.

DR. GRAY: Okay. Section (14), radiation output. The system shall be capable of producing a minimum output of something coulombs per kilogram or 500 milliroentgen per second. I am still not sure what a coulomb per kilogram is. I guess that is something I get at the grocery store, so many coulombs per kilogram.

MR. SHOWALTER: It's a tiny bit of exposure.

DR. GRAY: Pardon?

MR. SHOWALTER: A tiny bit of exposure.

DR. GRAY: We had three people that absolutely agreed with this. One additional person urged early implementation of this. One individual said this should apply only to the moly/moly system, it ignores the others, and it is detrimental to breast thickness from the point of view that if you specify it for this and not consider the other ones, you actually may be in better condition using other target filter combinations which could reduce the dose to the breast, especially the larger dense breast.

This is another one where people said -- actually, three people said to emphasize outcomes. What you are really interested in is the output at a particular kVp, so you can keep your exposure times below some certain value. That is really what you are trying to specify for a particular breast thickness. Another individual said this should be part of 21 CFR 1020.

Any comments regarding the radiation output, 500 mR per second?

Carl?

DR. D'ORSI: I guess this is mostly for -- well, whoever can answer it. What does 500 MR, et cetera,

translate to in generator size? Is that about a 100 mA generator, 50, 75, 150?

DR. HENDRICK: I think the 500 mR is easily achievable with about an 80 mA or higher, and the 800 should be achievable with 100 mA or higher, the 800 MR.

DR. D'ORSI: Because that could affect the mAs. If you have a lower generator, in order to get up to -- and I guess that is what these comments are aiming at -- you can get a much higher time.

DR. HENDRICK: But it is also related to the SID.

DR. D'ORSI: But that is fixed, too.

DR. HENDRICK: Well, not from one manufacturer to another.

DR. D'ORSI: Well, it will be if 55 is going to be lowest.

DR. HENDR ICK: That is the minimum.

DR. D'ORSI: Right, right.

DR. HENDRICK: But not the maximum.

DR. D'ORSI: Yes.

DR. GRAY: One of the reasons for putting this in was to make sure we didn't have these low-output units required when exposure --

DR. D'ORSI: That is right. I am thinking it should even be higher. One of my peeves is that these

generators that you often have to --- in order to increase your contrast without changing your kV, you have to go up on time, and you begin to get motion and sharpness.

I mean, I would like to see mA generators higher than 100.

DR. HENDRICK: Well, the spirit of this was to eliminate the truly low-output --

DR. D'ORSI: Right, yes.

DR. HENDRICK: -- inexpensive unit that was being promulgated as being satisfactory.

DR. GRAY: Okay. Any other comments?

Penny?

MS. BUTLER: I support this, but I do want to point out that one manufacturer submitted that it was going to be a $21,000 upgrade in order to retrofit for this on one of their systems.

DR. GRAY: Well, at l east you can upgrade and don't have to buy a new unit.

MS. BUTLER: That is some upgrade.

DR. GRAY: That is a forklift upgrade.

Any other comments?

Cass.

MS. KAUFMAN: I think there was an interesting public comment that said that compliance should be

determined with a phantom and the beam and that the exposure be completed within 2-1/2 seconds.

DR. GRAY: Well, I am not on the compliance issue yet. We are still on (i). The compliance is (iii).

MS. KAUFMAN: No. This has to do just with the output part, that the exposure should have to be completed within 2-1/2 seconds.

DR. GRAY: That is part of (ii).

(i) is basically just 500 and 800 mR per seconds.

MS. KAUFMAN: No, they are two different things. One says that it has to maintain the output for 3 seconds. In other words, it can't drift off.

I think what this commenter is saying, that to achieve the 500 milliroentgens per second, you should have to achieve that within 2-1/2 seconds. I think they are two different things.

DR. GRAY: Within 2-1/2 seconds.

MS. KAUFMAN: Yes.

DR. GRAY: That is rise time. You don't want that. You want short rise times.

MS. KAUFMAN: Well, that is what they are saying is that you should put something in here that doesn't allow them to achieve the 500 milliroentgens per second over a very long exposure time.

DR. HENDRICK: No. It is per second. So that is an output criterion.

DR. GRAY: It is an instantaneous measurement.

MS. KAUFMAN: Right. Thank you.

DR. GRAY: Okay. Does anybody have any problem with the 500 and 800 figure?

MS. BUTLER: Wait a minute. I think we should listen to the moly/moly comment.

DR. GRAY: Oh, apply the moly/moly to that, yes.

MS. BUTLER: Just to moly/moly.

DR. GRAY: Yes.

MS. KAUFMAN: It is my understanding that the manufacturer -- I think the output would be higher with rhodium. No, it is lower?

DR. GRAY: It is lower.

MS. KAUFMAN: Okay.

DR. GRAY: And yet, you get better penetration.

So we will make that for moly/moly, the 500 and the 800 for moly/moly.

MS. KAUFMAN: With rhodium, does it not meet this output? What is it with the rhodium?

DR. KOPANS: I think rhodium goes down to about 90. Isn't that what you operate at? It is 90 mA per second.

MR. SANDRIK: John Sandrik, GE Medical Systems.

Somewhere, rhodium/rhodium is at 28 kV. I think it is somewhere between 500 and 600 mR per second. I don't have the exact data with me. I am just kind of trying to recall from my comments here, but it is definitely lower.

MS. KAUFMAN: Well, that would meet the c urrent requirement.

MR. SANDRIK: It is meeting the 500 mR per second.

MS. KAUFMAN: Yes.

MR. SANDRIK: It will not meet the 800 mR per second, and so we are talking about having to develop a new tube if you really require 800 mR per second.

MS. KAUFMAN: I am wondering if we can just make the moly/moly applicable to the higher, to the 800 milliroentgen.

MR. SANDRIK: We have no problem with moly/moly.

MS. KAUFMAN: So leave the 500 applicable to all units for the earlier one, but make the 800 --

DR. GRAY: No, I don't think that is reasonable because the 500 -- the roentgen-per-second output is lower for the rhodium, but your penetration factors and everything get short exposure times.

MS. KAUFMAN: He just said it is between 500 and 600.

DR. HENDRICK: Yes, but we can't write the regs to suit GE.

The point is, the whole reason this was in here in the first place is to prevent low output, and if different manufacturers have different methods of dealing with, say, the dense breast which is thicker and denser, that provide lower-dose methods of getting good images in a short time, then we shouldn't be excluding that by these regs because they are getting adequate output to get images of dense breast in a sufficiently short time. It is just that they are switching to a higher beam quality to do that. So we don't want to prevent that kind of innovation.

DR. GRAY: This is actually one area where the emphasis on outcome, as noted up there by three commenters, would be helpful because you wouldn't be specifying the mR per second. You would be specifying an exposure time for a certain breast thickness, that sort of thing, but presently, it is not drafted that way.

MS. BUTLER: Joel? I'm sorry.

DR. GRAY: I am trying to move on.

MS. BUTLER: I know you are, but I think we should -- I would suggest addressing the 800 mR per second in the 5-year new equipment category that we have established.

DR. HENDRICK: To make it apply to newly acquired equipment?

MS. BUTLER: Newly acquired equipment.

DR. GRAY: Okay. Any objection to that?

[No response.]

DR. GRAY: Okay. So it doesn't require retrofit.

Item (iii), the system shall be capable of maintaining the required minimum output for at least 3 seconds. Any problem with that? It seems like to goes along with it.

Item (iii), compliance shall be determined. Shall we move this compliance information to, perhaps, guidance to the quality control test? It is not a quality control test because we don't want to do this on an ongoing basis. How about removing this to guidance?

MS. KAUFMAN: No. If you are going to have the output requirement, you have got to have how it is measured. You have got to.

DR. GRAY: Okay. Penny?

MS. BUTLER: I know it is not currently in the ACR manual, but I think this should be a QC test for requirement for equipment. Perhaps it should be moved to quality control.

DR. GRAY: It is an acceptance test. It is not an ongoing test. It is not something you would have to test on an annual basis.

MS. BUTLER: Unless the o utput degrades over time, which it does. I have seen it happen, and then you want to buy a new tube.

DR. GRAY: But in the spirit of minimizing the quality control test, this is one that we could leave out.

DR. HENDRICK: Yes. The choice is really do you want it to be done by the MQSA inspector or by the medical physicist because those are the two choices if you have it in regulation.

MS. KAUFMAN: But it doesn't even really require additional testing. It just requires a calculation.

DR. HENDRICK: No. It requires measuring output.

MS. KAUFMAN: Right, but I am saying you do that, anyway. When you measure dose, you are measuring output. So it is not even additional testing.

DR. GRAY: But we are not necessarily measuring dose at 28 kV. We are measuring it at the clinically utilized kV.

MS. BUTLER: No, but for example, it says you should measure kVp at clinically used -- and you know, there is a real good possibility that you are going to be

measuring at 28 kVp, anyway, but if you put it under the QC requirement, then it has got to go under our frequency. So would you want to look at this annually?

It is something I do now, and it is not a big deal.

DR. HENDRICK: Yes. It is a simple addition to the existing QC test.

DR. GRAY: What benefit does it have? The original purpose for putting this in here was to avoid the use of low mA output units.

MS. BUTLER: I see your point.

The purpose that is stated here, again, is really acceptance-related. The purpose that I --

DR. GRAY: It is not e ven acceptance-related. To me, it is more specification-related to the manufacturer.

Shall we move on, Penny?

MS. BUTLER: Yes, go ahead.

DR. GRAY: Okay. (15), automatic exposure control. The next overhead, please.

[Overhead.]

DR. GRAY: "Each system shall provide an AEC mode which is operable in all combinations of equipment configuration...grid, nongrid; magnification,

nonmagnification; and various target-filter combinations." There were several comments about that.

I remember a comment in ther e about not having to use all of the various combinations or to test it in all of the various combinations.

MS. KAUFMAN: Yes. It says one comment agreed with our recommendation that the requirements should be limited to clinically used configurations.

DR. GRAY: That's right. That's right.

Previously, we did recommend to limit it to those configurations. There were four comments about it, four additional public comments about it.

DR. HENDRICK: Right, so if they never used nongrid --

DR. GRAY: Rig ht.

DR. HENDRICK: -- in contact mode, for example.

DR. GRAY: Yes.

DR. HENDRICK: That shouldn't be tested.

DR. GRAY: Does FDA make a note on that so we can change that wording so it is "clinically used configurations" or "clinically useful"?

DR. FINDER: Again, what I would suggest is that we try and stay away from the word editing at this point.

DR. GRAY: Well, we are saying concept.

DR. FINDER: Right. We have got the stuff we got from April already. I have got it here.

DR. GRAY: Okay, goo d.

Item (ii), "The AEC shall be capable of providing automatic mAs selection." We recommended deleting that the previous time because that is the purpose of AEC is to provide automatic mAs selection.

Item (iii), "The AEC shall provide reproducible radiation exposures with a coefficient of variation not to exceed 0.05." I believe that is standard terminology and is probably the same as in 21 CFR 1020. Do we need it here?

MS. KAUFMAN: My only comment on that is a frequent complaint I get is having to reference a lot of different regulations. I don't care, personally, but I think it does make it a little easier on people if it is all in one place.

DR. GRAY: Penny?

MS. BUTLER: We do test it in the QC section.

DR. GRAY: Is it specified at 0.05 in the QC section? I would be surprised if it isn't. If nothing else, we should move this to the QC section.

MS. KAUFMAN: QC section doesn't talk about coefficient of variation. It says maintaining film optical density within plus or minus 0.3.

DR. GRAY: Penny?

MS. BUTLER: We should move it to the QC section.

DR. GRAY: Any objection to moving this to QC?

DR. HENDRICK: Which part are we talking about now?

DR. GRAY: Section (iii), "The AEC shall provide...a coefficient of variation...0.05."

DR. HENDRICK: No, there is no problem with that.

Can I just go back? I am confused now because, on (i), this is a requirement for equipment manufacturers per the facilities. It is a requirement on the facilities, but it is saying that the equipment needs to be able to operate with AEC in each of these modes, whether it is mag, with mag, without grid, or grid or contact without, contact nongrid. That is really an equipment capability. How they use it clinically is a separate issue, right?

DR. GRAY: That is a good point, yes. All this is saying is that the equipment must operate in all of those modes.

DR. HENDRICK: It is just when you switch something out, like take out the buckey, you still need to be able to use the AEC mode.

DR. GRAY: Yes. It doesn't say anything about testing.

MS. KAUFMAN: I think the biggest difference is this says that you have to have AEC.

DR. GRAY: Right.

MS. KAUFMAN: Right. Under QC, it doesn't say that.

DR. GRAY: Right. So this really is an equipment requirement, but it shouldn't be under the clinically used modes.

DR. HENDRICK: Right.

DR. GRAY: You should be able to have AEC under any mode you select.

Penny?

MS. BUTLER: A possible exception would be if you buy units strictly for screening and you don't have mag, for example.

DR. HENDRICK: Yes, that is true.

DR. GRAY: Okay. So we will leave this one with the FDA.

Item (iii) will be moved to QC.

Item (iv), "The positioning or selection of the active detector shall permit flexibility in the placement of the detector under the target tissue," and there are a couple of other items here, but public comments on that,

description of the detector position was vague. There were three comments to that effect.

You need increased flexibility to position the detector. Two people indicated you just may not want to move it in and out. You may want to move it side to side. For example, if there is a particular mAs, you want to either put it under or you want to avoid. You may want to be able to move it side by side.

Indicators. At least one person wanted a comment added that the indicator, the position indicator, shall not produce artifacts. There is at least one or two of them out there that I have seen that do, and indicators should be placed on the compression panel so you can see where those are.

Now, those are actually asking for additions to this. Do we have any comments as to the need for such additions?

The fact that the indicator shall not produce an artifact, we are going to find that on an artifact if it does, and it is going to have to be remedied. So I don't think it is necessary to add something to that effect, but the indicators on the compression panel --

MS. HEINLEIN: Excuse me. As far as the detector position being vague, I mean, it just says to permit

flexibility and placement, so it can be under the target tissue. I don't think that we should specify in which direction it should move and how it should move and how many little millimeters it should move in between them.

I think the way it is stated right now leaves it open and gives you the flexibility to make sure that you are achieving what it is you want to achieve. So I don't see adding anything in that.

DR. GRAY: In fact, the second concern there, increased flexibility, is not restricted in this definition as it is now. There is nothing saying that you can't put that detector 3 centimeters off midline or 5 centimeters off midline or anything like that.

So I would ask if item (iv) at this point, is there any objection to any of the items in there from the committee, any changes we see we need.

Ed?

DR. HENDRICK: Well, (B) is not met by a large number of the units that are out there now because the indicator is not visible from both sides. Sometimes it is not visible from either side. It is completely under the unit, under the image receptor assembly. So it is going to require pretty major retrofit for some units.

DR. GRAY: Or just placing it on the panel, compression panel.

DR. HENDRICK: No, but this is not just showing the possible locations, all of the possible locations. I think it is saying you need to indicate the specific one that has been selected and make that visible from both sides of the examinee.

DR. FINDER: In April, the committee recommended that "and visible from both sides of the examinee" be deleted.

DR. HENDRICK: Okay, I would agree with that.

DR. GRAY: Okay. "And visible from both sides" being deleted. So that still raises the issue of the selected the position of the detector shall be clearly indicated, and you are saying that means we have to have some type of active indicator rather than just marks on a compression paddle.

DR. FINDER: Right.(A) covers the marks on the compression paddle.

DR. GRAY: Right.

DR. FINDER: (B) covers which one is actually selected.

DR. GRAY: Right.

Is there any problem, any objection to that?

Penny.

MS. BUTLER: I guess a question I have, knowing where the position of the nub which moves the detector, the compliance with that statement?

DR. GRAY: Interesting question. Would that be in compliance?

DR. HENDRICK: If you can see it from both sides.

DR. GRAY: No, no, no.

MS. BUTLER: Taking that out.

DR. HENDRICK: I thought we struck the whole thing.

DR. GRAY: So just a slide on the side of the buckey would be sufficient to indicate where it is located.

MR. SHOWALTER: So long as the operator could determine from that where the detector was, sure.

DR. GRAY: Yes.

MR. SHOWALTER: Sure.

DR. GRAY: Is that a problem with anyone?

[No response.]

DR. GRAY: Okay, moving on. (v), "The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting."

Then, in (vi), it goes in to explain more of this in detail.

We recommended in the previous meeting that w e change the optical density to a 10 to 20 percent mAs change as opposed to specifying this in terms of optical density, and two other public comments pointed that out this time.

Another one said eliminate the reference to density, another two comments there.

Another comment was at what density do you want to do this at because that wasn't specified.

Another said the percentage of density is a meaningless number.

So I would ask that we look at (v) and (vi) together. (v) is, I think, a given. (vi) effective October 2005 or 10 years afterwards that we have to have that variable in four steps above and below normal, and that would be in 10 and 20 percent increments of mAs.

Is 10 years reasonable?

Penny?

MS. BUTLER: I think it should be for new equipment.

DR. GRAY: For new equipment. Any problem with that?

MS. KAUFMAN: I agree.

DR. GRAY: Okay.

MS. HEINLEIN: Joel, does that mean for new equipment, it goes into the 5-year, new equipment at 5 years?

DR. GRAY: Five years, okay.

MS. HEINLEIN: B ut by doing this new equipment at 5 years, that does mean that someone could, in effect, keep a piece of equipment. I know there is some equipment out there that only has one change in AEC density. That is all. So that, they could continue to use that equipment, then, if it met all the other standards.

DR. GRAY: Yes, that is correct.

MS. HEINLEIN: So they would just be manipulating kVp and the contrast and image quality.

DR. GRAY: Yes.

MS. KAUFMAN: Joel, there was one comment back under that previous section that said that we need to delete -- actually, there were three comments that recommended we delete the difference between adjacent mAs settings at the end.

DR. GRAY: That was because of the confusion it introduced relative to the previous specification of density, and this will be rewritten in terms of mAs only.

MS. KAUFMAN: Okay. Is that what we decided, it was only going to be mAs?

DR. GRAY: That is what we recommended at the last meeting.

Item (vii), we recommended that this be dele ted at the last meeting. Actually, items (vii)(A) and (B), the whole section.

MS. KAUFMAN: Joel, excuse me, but I think that the purpose of -- I thought that the propose of this meeting was to go over what the public's comments were, not what our comments were.

DR. GRAY: We did, but I want to emphasize that we have already recommended deleting some of these sections.

MS. KAUFMAN: But that doesn't mean that is what the public thinks.

DR. HENDRICK: But it is in this case. In this case, the public comments agree with what we did last time. So can't we go on?

MS. KAUFMAN: Yes, but I just think we need to make that point.

DR. HENDRICK: We did.

DR. GRAY: We did, I thought.

Robert?

DR. SMITH: Just to follow up on that point, I also heard that we were asked yesterday by FDA to make these

recommendations as we reviewed these comments for any streamlining, modification, greater inclusions or deletions.

DR. GRAY: Yes.

Section (vii), we previously recommended deleting this. Public comments were that this should only be required for one detector position; that the detector position wouldn't affect the numbers.

One individual claimed that the hell effect would change the density settings, depending on where you placed the detector. If you think about this, this is not a good argument because if the photo-timing system is working correctly, it will take the heel effect into account.

The other one was this should only be carried out for useful clinical kVp's, and there were loads of comments on this whole AEC section, probably the most comments of any of the ones I have reviewed here.

Let's go back to the fact that we recommended deleting this previously. Does anyone have any problems with that recommendation in light of the comments?

DR. HENDRICK: You are talking about (vii), right?

DR. GRAY: All of (vii), yes.

MS. KAUFMAN: So we wouldn't have any tracking requirements?

DR. HENDRICK: That would come under the physics QC testing.

DR. GRAY: Quality control.

DR. HENDRICK: I think it is app ropriate to have it in the physics QC testing because there is where technique factors can get recommended to correct any AEC.

DR. GRAY: And this is something that has to be tested on an ongoing basis because it is an adjustable item on the system.

DR. HENDRICK: Right.

DR. GRAY: Ruth?

MS. McBURNEY: You are just talking about the (vii) going, not (A) and (B).

DR. GRAY: Yes, (vii) and (vii)(A) and (B).

MS. McBURNEY: But (A) and (B) has to do with the equipment standard.

DR. GRAY: But it is all p art of (vii).

MS. McBURNEY: We were talking about moving all of this to QC, and it may be that that is not appropriate for (A) and (B) because (A) and (B) is more of an equipment standard for either new equipment or after that date, whichever.

DR. GRAY: Penny?

MS. BUTLER: I would like to suggest that it be handled in guidance, and actually, it is already out there in guidance right now. The new equipment is part of the ACR CDC, not precisely in this wording, but close, and not be included in the regulations.

MR. SHOWALTER: Let me just observe that, effectively, the requirements contained in (A) are currently contained in the QC requirements. So the effect of deleting (vii)(A) and (B) is to delete (B) ever going into effect.

MS. BUTLER: Right.

MS. KAUFMAN: And (B) tightens up the requirements for tracking on AEC.

MR. SHOWALTER: That is correct.

MS. KAUFMAN: And I think we wanted to do that.

DR. GRAY: Well, at the last meeting, we decided we didn't want to do it; that we delete the entire section. So where do we go?

DR. HENDRICK: I would suggest we do want to tighten the requirements in a staged fashion, but that that should be through the QC because that is where it is going to be tested on these units.

I understand Ruth's point that this is really an equipment performance requirement, but I think it is easier

to test it. I mean, the physicists test this, anyway. So that would be the place to implement it.

MS. BUTLER: In a staged manner like this?

DR. HENDRICK: I don't care. I me an, I think you have to stage it somehow because if you plopped (B) down when these things go into effect, you are going to have a lot of units failing.

DR. GRAY: Any objection to taking care of this in quality control and move the two limits to quality control?

MS. McBURNEY: I think it should be left up to the FDA on the most appropriate place to put this particular rule.

DR. GRAY: Is that satisfactory with FDA?

MR. SHOWALTER: Yes.

DR. GRAY: Thank you.

MS. KAUFMAN: There was one comment that fi lm manufacturers are allowed up to a .3 OD change from lot to lot, and therefore, going to the .15, you can't do it.

DR. GRAY: Why not?

MS. KAUFMAN: Because the film is allowed to have a .3 change.

DR. GRAY: But you are measuring this with one emulsion batch. We are talking about machine variability here and not film variability.

MS. KAUFMAN: I know. I am just reading you the comment.

DR. GRAY: That is why I didn't read that one myself.

Item (16), disabled examinees.

DR. FINDER: Excuse me. B efore you get to (16), I just want to make one comment. We did have some comments in there from people, I guess, who used Xerox machines indicating that this AEC requirement will take out Xerox from use. Now, whether that is a good thing or bad thing --

DR. GRAY: No. Oh, you mean the requirement for AEC?

DR. FINDER: Right.

DR. GRAY: I think it is a good thing, really.

What was the figure of the last time? There were 30 or 40 Xerox units still functioning? Was that the number?

DR. D'ORSI: Right , 30 or 40 too many.

DR. GRAY: Yes. So I am not sure if that is a major concern.

They can handle that through a variance; is that correct?

DR. FINDER: Yes.

DR. GRAY: Good.

Disabled examinees. "Each facility scheduling disabled individuals shall have equipment and established protocols to ensure the facility's capability to perform mammography adequately on such individuals."

[Overhead.]

DR. GRAY: Quite a few public comments on this. A couple of people commented that this should be handled or is handled by other Federal agencies through the ADA.

An interesting question was raised that most mobile facilities cannot accommodate wheelchairs. Is this going to be necessary?

One facility cannot accommodate all disabilities. I am not quite sure what is meant by that. Maybe somebody can comment on that.

You can't screen during scheduling because a lot of these patients are scheduled by their referring physicians and not by the patients themselves, and there were 14 comments to that effect.

Delete the requirement for protocols. They felt protocol, per se, was unnecessary.

Again, a comment, refer this to the Americans With Disabilities Act rather than duplicate the ADA.

An interesting question, how do you enforce this?

The requirement will preclude facilities from providing services to the disabled. Several people felt that this requirement, if they don't meet it, they will just tell the disabled person that they can go elsewhere, which I think is sort of forced by this wording. I am not sure.

Another person said that this is not a radiation issue, and therefore, it should be deleted, but we are not required, I guess, under MQSA to have these all be radiation issues. It is quality of service.

Any other comments or concerns about (16) and what we should recommend to the FDA on this?

MS. KAUFMAN: Is there some kind of a Federal law that says you have to have this in all new Federal regulations or anything? I mean, it may not be optional to take it out. I don't know.

DR. FINDER: I personal ly can't answer that.

DR. GRAY: What does the Americans With Disabilities Act specify? I know you have to provide access; is that correct? Reasonable access?

Amy?

MS. LANGER: The ADA is very general, but what it does specify for buildings and other facilities that the public visits is that persons with disabilities -- and they particularly mean wheelchairs -- can have accessible

interactions, which could include not only showing up and being able to go on a mobile van, for example, but also being able to be served there with the same level of service provided to the general public.

So I would imagine, although I am not an expert and I think it is an important question, that the ADA generally would suggest that a mobile mammography facility permit a person in a wheelchair access, but also be able to examine her.

I don't know, but I would imagine there is some sort of ramp system built into mobile vans to get the equipment on. I don't mean if that means a person could come on that way as well or whether it would not be the right place to enter, but ramp retrofitting is about the easiest possible thing to do.

The most important thing, though, in terms of this reg is the level of service provided to the person when she is there, and I think Marsha and I as consumer reps are very clear on this point, which is that if a facility cannot serve a disabled person, I don't know if we should or can require each facility always to serve a disabled person, but we suggested at a certain point that the facility be made aware, perhaps with the help of an accrediting body or the FDA, of a facility in a reasonably convenient location that

could accommodate her so that facilities that could not accommodate a disabled person would at least be able to provide her with a name of a place to go.

DR. GRAY: Wouldn't ADA require every facility to provide services?

MS. LANGER: I said I am not an expert in this. I would like it to be investigated, and actually sort of ironically, I had asked that that specific thing be checked prior to my own disability. So I don't know. Was it checked?

DR. GRAY: Larry?

DR. BASSETT: I just have to comment because we have this problem. We have a mobile. We really can't do wheelchair, not only because of not having the ramp, but because it is so small. The area and size is so small.

So what we do is we provide for those patients who want to have the screening done who enlist in the mobile recruiting a transportation to go to their main facility, and we do it there where we have more space and so on, and also people who are used to dealing with this.

MS. LANGER: I have a point that if you cannot accommodate the person, the idea is to find a way that she can be served. I think that is incumbent upon facilities

under ADA, but frankly, I am rather appalled that this hasn't been investigated.

MS. SCIAMMARELLA: I think what Larry said, we as a public facility are required to follow the guidelines of ADA. I mean, we can't accommodate people with private sector. In any facility that has to deal with the public as a public facility, you need to comply with ADA regulations.

Now, with the private sector, you can work out something, what is the facility, where is it located, and what are the arrangements, like has been mentioned.

DR. GRAY: Marsha?

MS. OAKLEY: Again, I have not researched it either, but my understanding always was pretty much what Larry has said that a mobile unit is really an extension of a facility, at least that is how I have looked at it, what little bit I know about it.

So, as long as the base facility had provisions made, thinking that you may be able to get into a mobile van, but not be able to maneuver once you are in there, that as long as the base ownership of the mobile van, as I have seen it used, you provide transportation, by appropriate transportation mode for a wheelchair-bound person back to the base, and that is how we had seen it handled.

I am also trying to think. I always think of Mike and his women who are out in the middle of Nowhere Land, and there isn't any access for that person. You really don't have a facility that has a ramp or can get her in. I don't know how to handle that. So that might be a question, Mike, only because I know you have some isolated areas. Maybe you can address that.

DR. LINVER: Generally, I think that this has been a problem for us. There is an access problem for the patients who don't have ready access to the van because of a disability.

DR. BASSETT: Can't you get an update of wheelchairs and do the examination on your mobile?

DR. LINVER: We can, but it has been a problem. It has come up relatively rarely because of the nature of the kind of imaging we are doing, but we have addressed the cases on a case-by-case basis, and sometimes we can accommodate them and sometimes we can't.

DR. GRAY: I would like to raise a question for Larry and Michael. Have you ever considered those chairs that they use in the airlines to move wheelchair patients down? They are very narrow. They don't have the big wheels on the side. That is a possibility.

DR. BASSETT: We have almost no space on a coach now. We can't carry extra things with us, period. I mean, we are really strapped.

What we do is we provide services to people who don't have access in the community in terms of just not having any facilities that will go down and do their mammograms. So what we do for those situations is what I recommended. We feel we have to have that accessibility for those patients, also, for the disabled patients who have to be on a wheelchair, but we are not doing it on the coach. I don't think we can do it, but we can look at it.

MS. OAKLEY: Since we have not looked at what the law says, we need to have the FDA folks look at the -- I mean, we assume and guess what we would do, but in the essence of time, I think the FDA folks need to look at what the law is and then make this an --

DR. PATTERSON: Charles has it.

MS. OAKLEY: Oh, he has got it.

MR. SHOWALTER: I, indeed, did download the ADA from Internet, found an actual use for Internet.

[Laughter.]

MR. SHOWALTER: I did look at what it requires. My recollection was that it was to the extent -- it was not an absolute requirement that every facility provide access,

but it was to the extent possible, to the extent practical kind of statement. It is very encouraging, but it is not mandatory that every facility provide access.

DR. GRAY: Rita?

MS. HEINLEIN: I think it is important that this stay where it is here. I disagree that we should take it out and just say facilities should know to comply with the ADA.

In talking with a number of technologists around the country and through lectures, often the comments are that they are so glad that this is in regulation that now, maybe, the facility will help them in being able to do patients with disabilities.

The problem is, even aside from mobile vans, that some of these "mammography rooms" are old bathrooms that have been converted, and they, too, are very small. They may not be able to accommodate a wheelchair. Many of them definitely do not accommodate a stretcher.

I think what is important here is perhaps not so much that we say that they must have the capability to perform, but to be able to say if they are not able to perform, that they are able to refer them to a place where they can get a mammogram, so it doesn't limit access.

DR. FINDER: Let me just say this. Again, in April, the recommendation was to include language something like "should make reasonable accommodations." So are we saying something different than that now?

MS. LANGER: Very specifically, Marshal and I both on this point made it clear that we think from a consumer standpoint that it would be very simple to provide through the accrediting body or the FDA some way to refer people to a facility that could accommodate them, and I know that we did make this point.

DR. GRAY: Ed?

DR. HENDRICK: Correct me if I am wrong, Rita, but my understanding is at some sites, they will say yes, we take disabled examinees, but when they get there, they can't do the full range of views on them; that the equipment because of its own limitations might be able to do a CC, but not an MLO or lateral. Is that part of the issue here?

MS. HEINLEIN: Yes. I think that not only is there an equipment issue. Yes, there is an equipment issue for some equipment that can't go low enough to accommodate persons in wheelchairs. There is a room size issue. So, yes, you are right when you are saying that.

That is why I think that we need to say it should establish a protocol either to ensure that the facility is

capable of performing them or to ensure, to give them -- I don't know what the verbiage would be, but to make sure that they have access to someplace where they know they could get mammograms, so that there is no limit of access for these people.

DR. GRAY: Carole?

DR. CHRVALA: Ed Hendrick and I have been doing repeated surveys.

DR. PATTERSON: Speak into the microphone, please, Carole.

DR. CHRVALA: Sorry. I will move closer. Thanks.

Ed Hendrick and I have been doing surveys i n Colorado on a variety of issues of the mammography centers that we have, a number of about 120, at least at this count, and this issue, we have asked about this issue in the last two, if not three, surveys we did, and it varied drastically.

What you said earlier, Rita, about the fact that the equipment -- I mean, what they say is accessible to the disabled. In reality, I think we need to be clear about defining what that means, and it means having appropriate equipment, people there who can assist the person to dress and undress. It is all over the board, at least, again,

this is from my experience in Colorado with 100 and some centers.

Our mobile units are not even trying that. I am disappointed to say that they are not making referrals. They are basically saying, well, you could come to our unit here in Denver, but we have a very vast geographic range in the high mountains and the very rural areas and the women aren't getting the service.

DR. GRAY: Can we leave this item (16) with the FDA with the understanding that they will talk to counsel and see what is required and craft the appropriate wording for this?

Elizabeth?

DR. PATTERSON: Yes. I think if they go back over our minutes from our April meeting, there were a number of suggestions, specifically, that women shouldn't be exposed if they weren't getting quality mammograms.

As far as protocols and equipment and in-service for technology --

DR. GRAY: Okay, so that was covered well, then.

DR. PATTERSON: -- and I think even the summary minutes cover quite a bit of the material that we discussed at that time.

DR. GRAY: Okay.

MS. KAUFMAN: One quick thing. I am hearing something about base mammo facilities. I just want to point out that there are a number of portable mammography companies that don't have a base site there to strictly portable companies.

DR. GRAY: I assume they have to be accessible, also, including the one that I heard about recently that does mammograms in the dressing room, in the ladies dressing room at the department store.

MS. LANGER: Joel, before we leave this, is it the sense of the committee still that there should be, if not the ability as Rita said to provide the service, access in-service; if that is impossible, to have some way to refer the woman on to a place reasonable convenient? Is that the sense of the committee? That was the sense last time as well.

DR. GRAY: I believe so, yes.

[Overhead.]

DR. GRAY: Item (17), X-ray film. "The facility shall use X-ray film for mammography that has bene designated by the film manufacturer as appropriate for mammography."

Vague. Public comment. Vague. Needs a standard for emulsion variability. Three people commented on that.

The FDA needs to implement inter- and intra-batch variability standards. Of course, somebody always agrees with it, also, and one person suggested adopting ACR storage requirements.

I like the last question. How do you know if the manufacturer's designated film is adequate for mammography?

Any comments?

[No response.]

DR. GRAY: The purpose basically behind this was to require that people don't use dual-emulsion films unless they perhaps were specifically designed for mammography; that they should be using a film that the manufacturer feels was designed specifically for that application. That is all I think that we were trying to get at there.

[Overhead.]

DR. GRAY: Intensifying screens. "The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography...," and we made a modification here at the last time, "...and shall select the screen appropriate for the film," meaning in terms of spectral sensitivity.

Somebody pointed out that this would ban zero mammography. Another person agreed with this proposed regulation, and I suspect it is the same person who raised

the question, how do you know if the manufacturer's designated screens are adequate for mammography.

Any questions or problems here?

DR. HENDRICK: It would seem to be appropriate to say for sites performing screen-film mammography.

DR. GRAY: Okay, for facilities performing screen-film mammography.

DR. KOPANS: Just out of curiosity, how would this be enforced? Who decides that a screen that has been selected is appropriate for the film?

DR. GRAY: The manufacturer designates that as such, and I believe that would have to go through the 510(k) process.

DR. KOPANS: I thought you were changing -- maybe I missed the change -- "as appropriate for mammography and select the screen appropriate for the film." Is it, then, "as designated by the manufacturer"?

DR. GRAY: That would be designated on the basis of spectral sensitivity.

DR. KOPANS: You said there was a rewrite of this paragraph.

DR. GRAY: Right.

DR. KOPANS: Maybe I need to hear the complete rewrite.

DR. GRAY: "And shall select the screen appropriate for the film," and I guess it is followed by "specified by the manufacturer of the film used."

DR. KOPANS: Because, otherwise, you could select a screen and say I think it is appropriate, and who decides that it is appropriate?

DR. GRAY: Right. It would have to be a spectrally matched system. That would be defined by the manufacturer.

DR. KOPANS: Make sure the language is clear enough so, again, it can't be circumvented.

DR. GRAY: Right, right.

DR. HENDRICK: The problem with the way this was originally written is it seems to specify that the facilities should do the spectral matching, and that is pretty unreasonable.

DR. GRAY: Right.

[Overhead.]

DR. GRAY: Item (19), film processing solutions, "For processing mammography films, the facility shall use chemical solutions that are capable of developing the films used in a manner equivalent to the minimum requirements specified by the film manufacturer."

One individual said delete "minimum," must comply, and the regulation should encourage more than minimum characteristics. There were six people commenting to that effect.

The facility should demonstrate the equivalence. In other words, where does the burden of demonstrating equivalence fall?

Some manufacturers refuse to acknowledge the equivalence of others products. A couple of people made that comment.

How is equivalence determined? If a manufacturer does not make chemicals, in other words, the manufacturer is going to have to specify somebody's chemicals other than his own.

One person said we agree, but guidance is needed on this, and then two other people said they just agree.

Any general comments regarding the public comments?

[No response.]

DR. GRAY: Okay, moving on.

[Overhead.]

DR. GRAY: (20), lighting. We did make a change in the wording of this, and I will read it as I understand it was modified or suggested to be modified. "The facility

shall provide a special light with luminance levels greater than that provided by the U-box." In other words, the facility should provide a hot light.

Dan?

DR. KOPANS: I apologize. Maybe this is a little silly, but lighting for viewing film screen images, I was thinking the light in the facility. You have to have the chandeliers turned up a little higher.

DR. GRAY: Good point. Maybe Charlie can clean that up when they revise this.

I thought you were going to comment that this doesn't apply to digital images.

DR. KOPANS: Oh, no. We back-light all of our digital images.

DR. GRAY: Oh, okay.

DR. KOPANS: Put the light right behind the monitor. It gives you much better lighting.

[Laughter.]

DR. GRAY: Any other comments on the hot light?

DR. MONSEES: May I ask this?

DR. GRAY: Yes, Barbara.

DR. MONSEES: Hot lights, would they technically have variable illuminance? I mean, it is on or off.

DR. GRAY: No. The variable illuminance was deleted from this or recommended the last time.

DR. MONSEES: Okay, thank you.

[Overhead.]

DR. GRAY: (21), film masking devices. "All facilities shall have film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film."

"Facilities using X-ray collimation that provides nonrectangular exposed areas...shall provide masking devices appropriate to these fields."

(iii) is, "Facilities shall make devices meeting the requirements" of this section available to the interpreting physician.

The last time we discussed this, we recommended deletion of items (ii) and (iii). I am not sure why we recommended deletion of the nonrectangular masks. Do you recall?

DR. HENDRICK: I think it is covered in (i), isn't it?

DR. GRAY: Oh, you are right. That is why, because it is not specific to rectangular or nonrectangular. Good.

So we recommended deletion of items (ii) and (iii). Are there any other comments or concerns about (21)?

The public comments were four people agreed with this. One person said it should be part of the physics survey and not part of the regulations. Expand. What they meant by this is they wanted the FDA to say not only should they be there, but they must be used, and I am sure Flo can figure out how you regulate something like that.

One person said that these things are expensive and cumbersome, and although they may improve interpretation, this is excessive regulation, but that was only one comment.

Any comments or suggestions regarding the comments and the proposed regs?

[No response.]

DR. GRAY: Okay. (22), film processors. "Film processors used to develop mammograms shall meet the following requirements: (i) The processor shall be adjusted and maintained to meet the technical development specifications for th employment film in use. (ii) Effective October 1, 2000, the processor shall indicate the selected time cycle...." It is specified what the time cycle is. Let's just leave it at those two for now.

So we are saying the processor must meet and process film to the specification for that film, and secondly, the time cycle or the development time must be displayed.

None of the public comments that I have noted up there are particular to these. They go on for some of the further ones.

Yes.

DR. KOPANS: Shouldn't that really be required for variable cycle processors? I mean, if you have got a fixed cycle processor, what is the point of displaying it?

MS. KAUFMAN: I think during our earlier discussion, it was decided it was really easy because, if it didn't already indicate that, they could just stick a label on it.

DR. GRAY: That is right.

DR. KOPANS: How much is that going to cost?

MS. KAUFMAN: A dollar.

DR. GRAY: The price of a piece of tape.

Rita?

MS. HEINLEIN: There was one public comment that says that if it is going to be mandatory to meet the film manufacturer's technical requirements, then it should be required for the manufacturers to make written guidelines

available as to what factors are needed to achieve maximum results from the film.

This has come out a couple of times. I don't know. This somehow needs to be addressed that this is made available to people so that they know what the technical requirements are.

DR. GRAY: This was the issue raised under the film, also, that the equivalency data has to be there. You are right. That data is not readily available on most films at this point.

MS. HEINLEIN: I don't know what the mechanism is to get that. I don't know if you can mandate that the film companies make it available.

DR. GRAY: So how can we put a regulation into effect if there is no way to get the data to implement it?

MS. HEINLEIN: Unless maybe, at least if it is in effect, it gives the facility at least something in black and white to take to the film manufacturer. It might help a little bit to get some information out of them.

MR. SHOWALTER: One hope with something like this, and let's assume for the sake of argument for the moment that this is not available, that if it does become a requirement, that, indeed, someone will make it available, and that individual or that manufacturer may well gain an

advantage and others may well see it that it is in their best interest to make this information available as well. That would be the hope.

DR. KOPANS: I interpreted this as being if you are going to change chemistries other than what are required by the manufacturer or what are suggested by the manufacturer that you show that the processing will be equivalent. Isn't that what you are suggesting?

DR. GRAY: That is one issue, but there are also issues about different types of developing processors. The idea here was just to make sure you got the equivalency out of the film, regardless of whose chemistry, whose processor you used or whatever.

DR. KOPANS: I think all manufacturers specify how their film should be processed.

DR. GRAY: Usually in their own chemistry, though.

DR. KOPANS: Right. Then, it would be up to the site to show that, in fact, if they are using different chemistry, it is coming out with the same H&D curve as the manufacturers recommended. Isn't that correct?

DR. GRAY: That may be the interpretation. I am not sure how the site would go about doing that, however, if they didn't have the data.

DR. HENDRICK: That is right because you have to do it in season chemistry.

DR. KOPANS: I thought that is what the requirement was saying is you have to do it.

DR. HENDRICK: Are they going to devote their processor to trying out the film manufacturer-recommended chemistry for a period of time and then switching it to their own?

DR. KOPANS: But isn't the purpose of the regulation -- because we have done this a lot. We fool around with chemistry all the time, but we are trying to improve on what the manufacturer has done, and there, you would ask for a variance if you think you have improved, but I don't understand why you can't show the equivalency, and have to show equivalency if you are not going to use the specified chemistry.

DR. GRAY: That is basically what we are saying has to be done, but the question is where do you get the data to show the equivalency.

Most of these small facilities that the question would probably come up in would not have the data and probably couldn't generate it themselves.

DR. KOPANS: You mean their high school equivalency physicists couldn't do it?

MS. KAUFMAN: I think what we we re trying to address here was the issue of the homemade kind of chemicals, the generic stuff that the little companies make themselves and that often aren't even close to the manufacturers. I think that is what we were trying to address is that you couldn't do something like that.

DR. HENDRICK: But this does get into pretty complex issues for a facility to sort through, such as if they are not getting the same H&D curve as recommended by the film manufacturer, is it due to the chemistry and the processor, is it due to the film batch that they received, what level of variation from the specified H&D curve do you allow, do you say is acceptable. It really gets pretty complex for a facility to sort through this and not have to call an expert in film processing in to do it.

DR. GRAY: Any other concerns or comments?

[No response.]

DR. GRAY: Going on to (iii), effective October 1, 2000, the processor shall be capable of maintaining developer temperatures of plus or minus a half-a-degree Fahrenheit.

The last part of that, starting with compliance measurements where it tells you how to measure it, the committee recommended deleting that the last time.

Comments regarding that, specs and display, development time. I am a little confused as to where these came from. These must be general comments.

Is there any problem with plus or minus a half-a-degree requirement? I think most processors out there today will meet that as far as I am aware.

Effective October 1, 2005, the processor shall clearly display the actual temperature within plus or minus 2 degrees of the actual temperature.

A question was raised as to where it should be displayed. We didn't specify that.

DR. HENDRICK: .2 of a degree.

DR. GRAY: .2 of a degree is the accuracy of that, yes.

Two people indicated this was needlessly expensive. I am not sure how much the manufacturers would charge to add this onto it, but you can buy a digital thermometer for about $150 to $200. So I wouldn't think it would be too much more than that.

Penny?

MS. BUTLER: The ERG report, the information they got was $300 for the upgrade.

DR. GRAY: $300? So you are talking about a $300 upgrade to a device that costs somewhere between 10- and $25,000.

One person indicated there was no clinical need. I guess I would take exception to that saying that when you are doing your process quality control, one of the things you should be monitoring is the processor temperature.

In many of these processors, in fact, the procedure is described here which we deleted to measure temperature, would require you to pull the racks out, and you really don't want to do that. You want to be able to monitor the temperature from the outside of the processor.

There were a lot of negative comments, in general, about the procedure. Specifically, three people said that we should get rid of that particular procedure for measuring the temperature.

DR. HOUN: I had a question on whether this is really needed.

DR. GRAY: Which?

DR. HOUN: The display.

DR. GRAY: It will not make the dif ference in detection of cancer, but it sure makes the job of the quality control technologist that is required to do daily processor quality control a lot easier.

DR. HOUN: That is nice to have. Is it essential for quality to have this display? You have a requirement for standard in terms of the temperature, but this display, is it essential for quality?

MS. BUTLER: I would like to suggest that we put some of these into that newly acquired category that we have.

For example, the temperature display, currently, a lot of processors don't have temperature displays, and the techs measure the temperature by hand. So it is not absolutely necessary. They do an adequate job of it as is. No question, it makes their life easier if they had it, but I don't think it is absolutely necessary.

MS. KAUFMAN: That wasn't going to be required until 10 years after implementation.

DR. HOUN: Also, the problem with 10 years is, then, again, if it is not essential that it happen right away, but we can wait 10 years, then is it --

DR. GRAY: Do we really need it?

DR. HOUN: Yes.

DR. HENDRICK: The variations in temperature will show up as variations in the sensorimetry done on the film.

DR. GRAY: Right.

DR. HENDRICK: So this first requirement of keeping the temperature within half-a-degree Fahrenheit is a little bit of overkill, but it is desirable. The display of the temperature, since we are testing things daily in the processor through sensorimetry, it is really just a luxury. If their sensorimetry isn't consistent, then they can look at the processor and see if the temperature is adequate.

DR. GRAY: Elizabeth?

DR. PATTERSON: Yes. What is the life of a processor? In other words, if you are putting something out there that you say it has to have a display in 10 years and processors are going to last longer than that and you have a processor now that doesn't have that display, are you going to have to replace it just for the nicety of having a display?

DR. GRAY: I would suspect that 10 years would be a reasonable life to configure on it because most of them tend to corrode or have problems before then.

DR. HENDRICK: We have plenty of processors older than 10 years.

DR. GRAY: Do you?

DR. HENDRICK: Sure.

DR. KOPANS: I am not sure it suggests a luxury. First of all, it doesn't sound like it is very expensive to

do. Second of all, you can measure temperature at the beginning of the day, but there are reasons. These systems can drift. You can be running into problems. Suddenly, you are starting to see degradation of the image, quite frankly, and you are trying to figure out what it is. Whereas, if there is a visual display, the technologist, hopefully, will appreciate that something is going on in the temperature.

I would make it sooner rather than later. I think it is more important that seems to be indicated h ere.

DR. HENDRICK: Does it need to be accurate to within .2 of a degree Fahrenheit?

DR. GRAY: That should be no problem with the equipment that is there today. That is not pushing the science at all.

MS. KAUFMAN: I agree with Dan that you only do the processor QC test once a day, and the temperature really can vary rather significantly during the day, and the idea is to try and catch this stuff before you see it on clinical images.

This, I think, is not a real expensive issue, and it would make it real easy to notice that.

DR. GRAY: Carl?

DR. D'ORSI: I have used that myself when contrast started to decrease, and with the water supply and

everything and weird temperature affects it. It has helped a lot to know the temperature, to glance and adjust the developer temperature. If it is a relatively cheap fix -- it is $300, I guess somebody said, to put in a digital readout -- to me, it borders on useful and not a luxury.

I mean, I can understand what you are saying. You can take the temperature by pulling off the top and just dipping a thermometer in and look, but people don't tend to do that. They will tend to look at a meter right on the machine.

DR. GRAY: Unfortunately, a lot of the processors, it requires more than lifting the hood.

DR. KOPANS: Well, then, it really is necessary.

DR. GRAY: At least one of the major manufacturers has a processor that the dryer lays on top, and you have to lift that up to get down into it. It is not an easy measurement to make in a lot of cases.

What is our recommendation? Do we leave the requirement for a clear display of the processor in at 10 years? Do we shift it for 5 years? Do we take it out completely?

MS. KAUFMAN: We could do l ike on the other ones and make it newly acquired equipment.

DR. GRAY: Okay, newly acquired equipment, 5 years. Any objection to that?

[No response.]

DR. GRAY: Okay.

MS. HEINLEIN: That is just (iv), correct?

DR. GRAY: (iv), yes.

Section (v), effective 10 years, processors with variable cycles, a selectable parameter shall be interlocked to prevent any initiation of changes in the parameters until any film in process is completed, and to prevent any new film from entering the process cycle until the variables are properly stabilized at the new cycle parameters. If there is an override for this interlock for maintenance procedures, the override status shall be clearly indicated to the operator.

Penny?

MS. BUTLER: I would like to propose that that also go in the newly acquired equipment category.

DR. GRAY: Five year, new equipment, yes.

Any other comments?

DR. HENDRICK: There were eight comments by commenters writing letters that said the requirements in Section 22 are unreasonable and that no equipment currently available can meet them, and it would increase the cost to

processors and mammography with no improvement in film quality.

I just thought eight comments was enough to make.

MS. KAUFMAN: Except if you look at that eight comments, I think they were all essentially from the same facility. So it may be, like, a duplicate letter. I am not saying that doesn't count.

DR. GRAY: Any other comments?

Ruth?

MS. McBURNEY: I just have a concern whether or not the manufacturers of the processors can do this in 5 years. Are they currently doing a similar type of thing?

DR. GRAY: I can speak for the high-end processor. The microprocessor control systems out there today all have this on it already.

MS. McBURNEY: Okay.

DR. GRAY: It is the less-expensive processors.

Are there any manufacturers here of processors?

[No response.]

DR. GRAY: It is the less-expensive ones that would be questionable.

Penny?

MS. BUTLER: Before we go away from this, I would like to revisit item (iii) in this section.

DR. GRAY: Okay.

MS. BUTLER: I just want to point out that one manufacturer replied that in order to comply with this item, on some of their systems, they basically have to replace the unit, $10,000.

DR. GRAY: You are talking about the half-a-degree processor control, item (iii)?

MS. BUTLER: Yes.

DR. GRAY: Does it identify the manufacturer?

MS. BUTLER: I am trying to find it.

DR. GRAY: The only processors I am familiar with that can't do that are the ones used in dental.

MS. BUTLER : It says industry personnel indicated that processors that are not currently in compliance with this requirement could not be corrected with a retrofit. Therefore, processors that do not have this capability require total replacement. That is what it says.

MS. McBURNEY: Did we make that one for new equipment only?

MS. BUTLER: We hadn't.

DR. GRAY: As it stands now, it is for 5 years.

MS. McBURNEY: But on all equipment?

DR. GRAY: That is correct.

MS. BUTLER: Correct.

MS. McBURNEY: Maybe we should make it for new equipment.

MS. KAUFMAN: How big a deal is it to put in a better thermostat?

DR. GRAY: It is not the idea of a better thermostat. The dental processors I am familiar with do not have recirculation, and they do not have temperature control systems at all.

MS. KAUFMAN: Right, but we are talking about for doing mammo films.

DR. GRAY: Well, I am not sure what this processor is. I am not sure who they are referring to.

I guess before I would feel comfortable about deleting this or making changes in it, I would like to find out who the manufacturer is and how many units are out there.

Personally, if they can't control the temperature to plus or minus half-a-degree, I am not sure they should be processing mammography film in them.

So are you comfortable if it is 5 years and new equipment?

MS. BUTLER: No, I actually tend to agree with you that we should have the control on all equipment, but I did want to bring it up because this is a major cost item.

DR. GRAY: Shall we leave it as it is for now? Are there any strong feelings one way or the other? Leave it? Okay.

Elizabeth?

DR. PATTERSON: Okay. Thank you very much, Ed and Joel.

Now, I want you to know that we have completed yesterday's agenda, okay? We will be starting after lunch, which we will reconvene at 1:45. We will reconvene, and we will start with today's agenda, basically, and we will finish today's agenda before we leave tonight.

So I suggest you eat a good lunch, and you may end up having pizza in tonight, seriously, because we have a lot of material that we have to cover yet, and tomorrow is all on accreditation bodies. So I can't allow today's stuff to go into that tomorrow.

So, out front there, they may take your order for pizza or what have you, but seriously, we will finish tonight, and for those who have been on the committee before, you know that I am a real stickler for finishing up what has to be.

Yes, Amy.

MS. LANGER: Madam Chair, could I ask that all the committee really keep their remarks brief? I think we all

kind of get into a stream of consciousness which is interesting, but I think we really could do a better job, all of us, of keeping our remarks concise.

DR. PATTERSON: I agree, and hopefully, we can. I don't like these midnight sessions, but we will finish today's agenda.

Enjoy your lunch. Make it good.

[Whereupon, at 12:30 p.m., the proceedings were recessed, to be resumed at 1:58 p.m.]

A F T E R N O O N S E S S I O N

[1:58 p.m.]

Radiologic Technologists

Retention of Personnel Records

DR. PATTERSON: We are going to reconvene.

We will have to forgive Alan today. It is his birthday. So we will forgive him for being late.

[Applause.]

DR. PATTERSON: He would really appreciate it if we could finish up in time for him to at least have a little bit of activity this evening.

One other request is some of you are talking before your mikes are turned on, and it is not getting on the transcription. Please make sure that it is on before you start saying what you have to say.

Let's pretend like it is 8:00 a.m., and we will do the technologists and the retention of personnel records.

Rita?

To get you into where we are, that is 14907 and 08.

[Overhead.]

MS. HEINLEIN: Good morning, since it is 8 o'clock in the morning.

[Laughter.]

MS. HEINLEIN: We are on page 14907, starting with (2) in the third column for the radiologic technologists. (i), under the general requirements, I wanted to put this up first, just some general comments that came in. I think it is already something that the FDA is aware of, that there is no grandfathering, so that there would be no one that was qualified.

Some of the 92 comments commented to grandfather those RTs who had met the interim regulations. One stated that as long as the technologist by October 1, 1997 had either 40 hours in training or 20 hours and their M, their advanced certification, others, many of the 92, just said grandfather in those technologists who have shown that they have their advanced certification, who have M.

Three comments under the general comments. Supported the documentation of proficiency testing. One stated that it should be evaluated by the lead interpreting MD. As we get into it a little bit farther, there were some other comments, though, that said that there should not be proficiency testing, that it would be too costly.

Moving down to general requirements, I thought it was interesting that there were 33 comments, 33 written comments, stating under (A) that they be licensed to perform general radiographic procedures in the State, emphasizing

that the licensure should be in the State where they are practicing, as it is with the physician.

Are there any additional comments on (A)?

MS. McBURNEY: That would be a little difficult for those in the military, wouldn't it? If they were not practicing in a State?

MS. HEINLEIN: In the State?

MS. McBURNEY: Yes. Or, if they practiced in several states -- well, they wouldn't be practicing in several States at the same time. Or, if they were practicing overseas or something.

MS. HEINLEIN: Right. I don't know that the 33 written comments addressed that issue at all.

Any other comments to that effect?

Yes, Cass.

MS. KAUFMAN: Under physicians, it says a State.

MS. HEINLEIN: Oh, it does?

MS. KAUFMAN: Yes.

MS. HEINLEIN: And physicists.

I just thought it was interesting that 33 comments would pick up on that and the semantics of that.

Yes.

MS. HAGERTY: I am Judy Hagerty with the Mammography Accreditation Consultants.

I have worked overseas not as a military tech, but actually as an X-ray tech who is a dependent wife, and this would also hit the dependent wives who were living overseas.

There were times when the military tech was transferred out and there was no one to take the place, and I actually took the place at two different sites of the military tech that was doing radiologic exams.

Now, there are mammography exams being done overseas in military facilities, and if you keep it to the State, it would make it difficult for the mammography techs who are military wives doing it overseas. I was just making a comment on that one comment.

MS. HEINLEIN: Thank you.

Ed?

MR. BAILEY: Ed Bailey from California.

I don't know whether this goes to why a State is important or why somebody said "the," but we have been approached by some people in States that do not have State licensure to be licensed in California so that they didn't have to be ARRT or they could meet the requirements for ARRT.

MS. HEINLEIN: Ed just got a call from a technologist commenting on that.

[Laughter.]

MS. HEINLEIN: Elizabeth?

DR. PATTERSON: Just to make a comment that they are probably the same 33, but there were letters, also, under the physicians saying "the State" instead of "a State."

MS. HEINLEIN: Is there a feel? Do we want to make any particular comment to the FDA in that regard?

Charlie?

MR. SHOWALTER: Let me just tell you why it is that way. We first confronted this issue particularly with technologists and with medical physicists from a point of view of if an individual is licensed in one State, the first example that came to my attention was licensed in West Virginia. They were practicing in Virginia.

From the Federal point of view, if the individual was licensed in West Virginia and practiced in West Virginia, that would be fine. We wouldn't care.

Then, why should we care if they are practicing in Virginia if it is okay with the State jurisdiction? Now, Virginia happens to be a State that does not license radiologic technologists, and so there was no issue there.

It is really that plus the military situation where physicians, technologists practice all over the country. They do, perhaps, practice in different places at

once because they do temporary duty. They fill needs in different areas. The requirement there is to be licensed in a State. It would create, I think, some difficulties for us as a Federal program to try to enforce particular State licensure, which is what this would be.

The States certainly are free to enforce that on their own.

MS. HEINLEIN : Dan?

DR. KOPANS: I am just curious. If all of MQSA is to have high-quality imaging, are there States that you can be licensed in that really don't require any training or demonstration? In other words, can I go in, in a State, and pay for a license to be an X-ray technologist?

MR. SHOWALTER: I am not aware of any. I believe that it is a fairly consistent licensure program from State to State, as far as I am aware.

DR. KOPANS: For those that do license.

MS. HEINLEIN: Any other comments concern ing the general requirement?

[No response.]

MS. HEINLEIN: There were six comments that came written in under the general requirements, just saying that spot-checking on films every 3 years was a very good idea. I don't know if that can also be incorporated into some

other things, but since it was written in under the general requirements, I made the comment here.

All right. Then, let's move on to the next slide.

[Overhead.]

MS. HEINLEIN: Under the mammography requirements, I think it is interesting that this morning we heard a couple of comments from previous speakers. Twelve people made comments on something, and that was certainly a reasonable number for us to pay attention to.

Also, we discussed making changes this morning, just coming in from one or two comments.

Well, before I realized that the ERG had counted all of these, I sat down and made little hash marks on every letter that I read and all the different comments, and I really was astounded to see that there were over 550 written comments concerning acceptance or recognition of the advanced certification exam.

I think that is really a very substantial number, and I think it lets all of us know how the technologists in this country feel about that advanced certification exam.

320 commented that it should be required. It should be recognized as a requirement. Eighty-nine commented that the M plus 40 hours should be required.

Then, there was a wide range on how much should the M fulfill as part of the 40-hour training requirement. Five said it should count for 5 to 10 hours. Twenty-two people commented that it should count for at least 20 hours. One said somewhere between 20 and 30 hours. Four commented that it should be 24 hours. Seventy-nine said it should count for the entire 40 hours, and 11 just made the comment that it should count as partial fulfillment.

One of the interesting letters that came in said that if people are taking continuing education classes, we all know that people can sleep through these continuing education classes, but you cannot sleep through this advanced-level examination.

I think in some of the other comments that came in, it said failure to recognize the certification in mammography is harmful to the field. RTs will have no reason to obtain the certificate. The law would discourage the profession to improve itself.

You need not to state that it specifically endorses it, but should address it as it is done under the interpreting physician, and I will comment on that later on.

Another one commented , recognizing the M, RTs have worked very hard to have mammo recognized as a specialty.

Don't take the recredibility of this exam away. This exam or its equivalent should be mandatory, it is in my State.

Another said, since its inception in 1932, the ARRT has always promoted the highest standards for education. "There is no justification to even consider that their standards would be lowered and 'diminish the integrity of the mammography exam.' The AART exam should be recognized." Then, it was stated, the Secretary of HHS recognizes it.

I am certainly not going to take the time to read all 550-plus comments, but in lieu of that, does anyone have any additional comments to add to that?

Dan?

DR. KOPANS: I apologize for not knowing the discussion that went on previous to this about this issue, but it seems to me we have been talking, at least yesterday, about measures of competency and so on. There is at least an examination that most of accept as demonstration of a certain level of competency. What was the reason for not recognizing the exam?

MS. HEINLEIN: Charlie?

MR. SHOWALTER: It is not recognized in the same way that it is not recognized under the interim regulations, and let me clarify that. Requirement for training is the

requirement. We do recognize the M as completing training under the interim regulations. We would recognize it for a certain portion of, depending on how this discussion comes out, possibly all of the 40 hours of training required under the final regulations.

The fact that it is not mentioned in the regulations doesn't mean that it won't be recognized as a practical matter, just as it is under the interim regs.

MS. HEINLEIN: Elizabeth?

DR. PATTERSON: I think one of the comments that was made during the discussion regarding this was for the training requirement it fit, but there was no experience that was required for the M. In other words, somebody could pass the exam without ever having done a mammogram. If I remember correctly, that was part of the discussion at the time.

MS. HEINLEIN: Yes, I think that is right, and that is why there are additional comments on the performance portion of the 50 exams under direct supervision.

The comments that were made here, these 550-plus that I read, many of them said that, in addition, there should be some type of clinical competency or there should be performance of clinical exams, and then, others just said

no. As you can see, 320 said no, that it should just be required.

Cass?

MS. KAUFMAN: Do you know how many technol ogists have taken and passed the mammography part? Was it about 550?

MS. HEINLEIN: Oh, no, no, no. No.

[Laughter.]

MS. HEINLEIN: I know that it is 20,000-plus that have taken it.

MS. KAUFMAN: I am not against it. I think the mammography thing is a very valuable thing, and I think we do need to give it a lot of credibility, but I suspect that all of those people have taken the exam.

MS. HEINLEIN: Oh, sure.

MS. KAUFMAN: I was just going to reiterate what Elizabeth said in that you don't have to have even taken a mammogram to take and pass that test.

MS. HEINLEIN: Right. I think that everyone agrees that the test does show credibility of cognitive knowledge, and for that reason, there was the inclusion of additional clinical proficiency, too.

Dan?

DR. KOPANS: I was just going to second that. I think that I wasn't suggesting that the test should be the only determinant, but I think it is a good way of measuring the 40 hours of classroom work, if you will, and to see that that has actually been learned, and then, in addition, I think, obviously, you need direct hands-on clinical work as well.

Again, we are all fishing for measures of certain levels of competency, and that is one that I haven't heard anyone disagree with. I may be wrong about that, but I haven't heard it. So it would seem to me that it should be incorporated as part of the requirement to do mammography.

MS. HEINLEIN: Yes.

MS. OAKLEY: I was just absolutely overwhelmed by the number of comments that came in. A lot of the comments that I know you got were on my consumer complaint sheets. I was just astounded at the number that were in there, and I think that speaks very well for this organization. Even if there is 20,000, even this percent took the time.

A lot of them were letters that were duplicate, but they were signed separately.

MS. HEINLEIN: Right. In fact, in speaking to that, I was very impressed to see that there were duplicate letters in there, but signed by the Mammography Quality

Assurance Committee. I mean, a whole committee got together to discuss this.

I know that I have heard at different meetings where there were actually mammography societies, mammography technologist societies that appointed boards to get together and take sections of this and review it and have discussion. So I think that was part of the reason that there were, perhaps, more than one letter signed by different people.

Any other comments on the M?

Yes, Cass.

MS. KAUFMAN: I think one of the concerns was that ASRT and maybe ARRT, also, only gets 24, I think, credit hours for passing the mammography examination, and that is, I think, why FDA was thinking that it would be equivalent to 24 hours, but I don't think that we have to use that analogy.

I think the only reason why they picked 24 hours was that they require 24 hours every 2 years, and they give you credit for passing any of their examinations in lieu of taking the 24 credit hours of continuing education. So I think that that analogy isn't necessarily a correct one, and in fact, I suspect that it takes maybe more than 40 hours to really prepare for the examination.

So I think that it would be very reasonable to give them credit for the 40 hours of their ARRT(M).

MS. HEINLEIN: In fact, in support of that, a couple of the letters made a comment that the M should count towards the 40 hours. It takes longer than 40 hours to prepare for this test, and there were many, "I spent over 40 hours studying for this exam." The AART represents the ASRT. It should be required for all mammographers, and then, it just goes on and on. After that, it is pretty much reiterating the same thing.

Any other comments on that? So is the feel of the committee that the mammography requirement would be to say that they shall either have advanced certification through an improved board in mammography or have undergone 40 contact hours of contact training, one or the other? Are there any feelings that there should be M plus so many hours of training?

Flo?

DR. HOUN: One is whether the M would be in lieu of the training in anatomy, physiology, positioning, compression, and the performance of a minimum of 50.

MS. HEINLEIN: I don't think it would be in lieu of the performance of the minimum of 50. I think it would

only be in lieu of the training in anatomy and phys and compression, et cetera.

Is there any agreement or disagreement on that from the committee?

Charlie.

DR. FINDER: I would just ask one question. You have changed the wording. Does it change what happens in reality?

We have said that there are two approaches. You can either have the ARTM or meet the 40. Whereas, here, we say you have to meet the 40, and part of that can be -- or all of it, if we decide, can be the ARTM. There is no change in the requirement. You have changed the wording, but the end result is the same. Am I mistaken?

MS. HEINLEIN: I think so. I think it would be that you either do the 40 hours of training or you have an M.

DR. FINDER: Right.

MS. HEINLEIN: And in addition to the M or the 40 hours of training, you would have 50 exams under supervision.

DR. FINDER: Right, everything else is the same.

So, in other words, what we have just discussed here doesn't change anything. It changes the wording and

how it looks, and there is some recognition of the M in the regulation rather than putting it into guidance or whatever, saying this is one way to meet it.

MS. HEINLEIN: It doesn't change what is written here. It adds to something that is written here.

DR. FINDER: But the end result is you can eithe r do one or the other.

MS. HEINLEIN: Correct.

DR. FINDER: Okay.

MS. HEINLEIN: I think I understand what you are saying. I am not sure I understood what you said.

DR. FINDER: What I am trying to get at is that, in practice, what you have suggested in terms of rewording it doesn't change what people have to do. There is no difference, as I understand it.

MS. HEINLEIN: Dan?

DR. KOPANS: Why not require the M?

DR. FINDER: Well, that is a different issue.

MS. HEINLEIN: I think the issue of wheth er or not to require it is for those technologists who work in a State that have State licensure who are not RTs. They are not certified through the ARRT as general technologists. Because they do not have that general certification through

the ARRT, they are not eligible to sit for the advanced certification.

So, to require the M would mean that those people that are only State-licensed would not be able to do mammography.

DR. BASSETT: Or they would have to get their ARRT.

MS. HEINLEIN: Or they woul d have to go get their ARRT.

I know that particularly in the State of New York, I don't know the number, but I have worked with a number of technologists in the State of New York who have a full State license. They have trained in other countries, and they have reciprocity. They sat for the New York State exam. So they are LT. They are licensed radiologic technologists.

DR. KOPANS: I don't know if you can do this, but why not require that they have some State test of competency in mammography comparable to the M?

MS. HEINLEIN: Any additional comments on that?

Flo?

DR. HOUN: The statute says that a requirement for the technologist is to be licensed by a State to perform radiologic procedures. So we can't go against that.

DR. KOPANS: But can't you require that they demonstrate additional competency in mammography with a test comparable to the advanced certification of the ARRT?

Again, we are going for quality here.

MS. HEINLEIN: Right.

DR. KOPANS: We have got to measure quality that exists in most of the country. No one has argued about it except the States that don't, I guess, use the ARRT or ASRT or whatever the acronym is.

It would seem to me, we would want to promote that rather than say, well, you can get around it, sitting for 40 hours, and I don't know that that really works.

MS. HEINLEIN: Has the FDA heard anything from the ARRT about the possibility of them taking their exam and making it available to other people that are licensed technologists?

MR. SHOWALTER: We have not appro ached the ARRT, nor have they approached us, to my knowledge, about that. That, certainly, theoretically, could be done.

MS. HEINLEIN: I know there was some discussion. I heard it spoke with someone at the ARRT, and there were discussions supposedly at the ARRT board level of saying that, perhaps, they could work something out if it was

needed that technologists would be able to sit for the exam, the advanced certification exam in mammography.

MR. SHOWALTER: Right. I mean, one of the issues right now, I think, as we first looked into this was the numbers. If we made the ARRT(M) a requirement, we would cause a huge access problem because there just simply weren't enough technologists with the M to serve the country.

That is not to say that this couldn't be set out somehow as a desirable goal and that we could work towards it. It is just simply not practical at this time, as I understand the numbers, to set this out as a requirement.

DR. KOPANS: What are the numbers? Do you know?

MR. SHOWALTER: I don't recall offhand. It has been 2 or 3 years since I looked at it, and it could have changed a fair amount since then. I don't know.

DR. HOUN: I think it is like one-third or so do not have it.

DR. HENDRICK: One-third of the technologists who do mammography don't have the M or one-third of technologists?

DR. HOUN: One-third of technologists who do mammography.

MS. HEINLEIN: Do have it or do not?

DR. HOUN: Do not.

MS. HEINLEIN: Any additional comments?

Penny.

MS. BUTLER: I just wanted to add something to Charlie Finder's question on does it change the reality of the situation.

I think the reality that it does change is basically the acceptance of these regulations out there. There was a huge number of people writing in about this one thing, and I think changing the wording to recognize something changes perception, albeit not what eventually gets required, and I think that is an important issue.

MS. HEINLEIN: Ed?

DR. HENDRICK: The other thing you have changed is the circularity of the language as it exists in the proposed rules, which is that if you make M equivalent to having 40 hours of documented training, it breaks the circularity which requires you to have 40 hours of supervision of someone who is qualified, but to be qualified, you have to have the 40 hours, and nobody is initially qualified. So it sets apart a group of people who are initially qualified so that they can train other people. Otherwise, nobody can ever qualify under this, the way it is written.

MR. SHOWALTER: I think the recommended change in grandparenting fixes that, also.

DR. HENDRICK: Yes.

MS. HEINLEIN: Any other comments? So is the feel of the committee, then, that it should stay that they have advanced certification or 40 hours of training? That would only take care of (ii)(A).

Okay, everybody is all right with that.

Esther?

MS. SCIAMMARELLA: What is the situation in Puerto Rico?

DR. HOUN: I don't know specifically about Puerto Rico.

MS. HEINLEIN: All right. Other comments that came in, 17 comments said that 40 hours was not a sufficient amount of training. Thirty-five commented that the 40 hours were very important, and two commented that under direct supervision of a certified technologist with an M, only one person said that 40 hours was excessive, and this was out of thousands of comments from these technologists.

519 comments said lack of recognition in the regulations meant the M would have no value. Well, I think we have already commented on all of that.

All right, I think that i s good. We can go to the next slide.

[Overhead.]

MS. HEINLEIN: Next, moving down to (B), "The performance of a minimum of 50 examinations under the direct supervision of a qualified technologist."

Two comments -- oh, I'm sorry. The training. I'm sorry. This covered the training. Two comments said that it should cover all aspects of quality assurance. Six comments said that we should add technical factors, film critique, pathology, and mammography of women with disabilities. One comment just stated that the physics should be taught by a physicists, signed by a physicist.

One comment said add a course on patient communication. Then, there were a couple of interesting comments. Old-timers who receive their training on the job did not have such training and may have trouble getting it. Again, I think that brought in the grandfathering issue.

New technologists need 40 hours including implants, but not experienced people. Again, I think that is the grandfathering issue.

Clarify if 40 hours is in a ddition to any previous training. I think there was some misunderstanding on that.

I think the portion to address here is the total of the eight comments. That is elaborated on what should be included if someone takes the route of the 40 hours of documented training. The comment on should we add anything to what is listed under (A) as far as training and anatomy, physiology, positioning, compression, QA/QC.

Any comments on whether they feel we should add anything on technical factors, film critique, pathology, mammography of women with disabilities, quality assurance? Any comments from the committee on that?

[No response.]

MS. HEINLEIN: Keep it the way it is?

Carole.

DR. CHRVALA: This may not be the place to address this, but one of the areas that we might include under this would be training in terms of understanding the statistics that they would be collecting or their outcome data that they might be collecting, which at this point is not addressed. We don't have a formal training program for that, but potentially, it would be important if we get into the medical audit situation and that is an ongoing piece of things.

MS. HEINLEIN: Any additional comments to that?

Yes, Joel.

DR. GRAY: I would assume, maybe incorrectly, that technical factors and film critique would be included under quality assurance and quality control. That is part of that.

MS. HEINLEIN: Okay. Penny?

MS. BUTLER: To address Carole's comment, I think that should be really under the physicians section, and that may be more appropriate to address that there.

MS. HEINLEIN: Mike?

DR. LINVER: I would agree, although I must say in some information I have seen about who is actually collecting audit data, it does fall upon the technologist in many facilities to collect these data. So I am not sure it is all so cut and dry.

MS. HEINLEIN: Well, I think one thing to remember is that these 40 hours -- first off, it is only 40 hours, and this would be taking a brand-new technologist that doesn't know anything about mammography and in only 40 hours of time teaching them about anatomy, phys, positioning, exposure factors, physics, et cetera, et cetera. Is there enough time within this 40-hour time frame to also include classes or whatever on statistics?

DR. LINVER: That is a good point.

MS. HEINLEIN: Gilda?

DR. CARDENOSA: I would agree with the comments that have been made that that really should fall under the interpreting physician. I think it would be a mistake to delegate that to the technologists.

MS. HEINLEIN: To p ut it into regulation?

DR. CARDENOSA: That is correct.

MS. HEINLEIN: Joel?

DR. GRAY: The way I read this right now, that that 40 hours includes doing 50 examinations, also.

MS. HEINLEIN: Yes. We will address that when we get to the 50-hour part because there were a couple of comments about that.

DR. GRAY: Is that the way this is meant to be? Is this worded correctly?

MS. HEINLEIN: I don't know.

DR. HENDRICK: I think he is right, the way this is constructed, but I don't think that was the intention, was it? The 40 hours would be (A), and then, (B) would be separate from that, is my understanding.

MS. HEINLEIN: Yes. I think that was the intention. The 40 hours would include just the didactic, and in addition to that, there would be 50 exams performed under direct supervision. That was my understanding.

DR. GRAY: This may be micromanaging the text, then, but I think that should be changed.

MS. HEINLEIN: Right.

DR. FINDER: Let me just bring up a point, again. We are talking about exactly what we did in April because that was the recommendation then. So it is nothing new.

MS. HEINLEIN: Okay.

Cass?

MS. KAUFMAN: I know we made significant changes in April in this section, and I don't remember exactly what they were, but I don't recall. Under, for example, the medical physicists, we keep bringing up this term "grandfathering," and under the medical physicist section, it talks about the effect date of the regulations, experience must be acquired under the direct supervision, but we haven't done that under the technologist. Was that a correction we made? And if it wasn't, I think we probably need to do that.

Right now, it says they have to do 50 exams under direct supervision, and that would apply to everybody. Again, we get back to who is a qualified individual thing. So we didn't do that. We probably need to.

MS. HEINLEIN: Charlie, can you remind the committee of what changes we have made as far as the possibility of grandfathering from the April meeting?

DR. FINDER: I thi nk you recommended that they be grandfathered.

I just want to bring up one other point in terms of (A). In April, the committee did recommend additions.

MS. HEINLEIN: What were they?

DR. FINDER: Patients with disabilities and examinees with breast implants to be included in (A), part of the training.

MS. HEINLEIN: I do believe -- and you will see when we get to the implant portion -- that implants should be included in the 40 hours of training as part of the positioning.

There were 550-plus commen ts on recognition of the certification. There were, like, 300 and some comments on the implants. Most of those comments led toward not specifying a number of hours, but to, instead, include that within the 40 hours of training, specify it there.

DR. FINDER: There weren't that many changes. If you want, I can quickly go over them, what was recommended.

For (A), before it gets to (A), it says the 40 hours of documented training shall include, but then you recommended it not be limited to.

MS. HEINLEIN: Yes.

DR. FINDER: Then, those other additions, you did recommend that (B) be changed to a new number which would take it out of the 40 hours. You did recommend that it be done after the training.

Then, for (C), you recommended getting rid of at least 5 hours of training in imaging examinees with breast implants and just start at least 8 hours.

MS. HEINLEIN: Yes. Shall we wait until we get to the next part?

DR. FINDER: Yes.

MS. HEINLEIN: Cass?

MS. KAUFMAN: Those changes have not corrected what I have just mentioned. We just need to make sure we get that in, because otherwise, this is going to be really mucked up.

DR. FINDER: I am not saying that. I am just trying to tell you what was changed.

MS. HEINLEIN: Before we move on, perhaps we need to make suggestions as to what should be included under "grandfathering" for those technologists.

Are there any ideas from the committee what should be included?

I can tell you that a couple of the letters made suggestions that -- actually, one of them, I thought, had some pretty nice verbiage -- that those technologists who met the initial requirements by 10/1/97 through either 40 hours of training or have their M would be grandfathered in.

MS. McBURNEY: That would be practicing technologists?

MS. HEINLEIN: Yes. That was what one comment made.

Another one -- actually five other comments said that if you qualified under the interim regulations, you should qualify under the final regulations, to make that the grandfathering clause.

Any comments o r suggestions on either one of them from the committee?

The first one. I have one vote that they have their 40 hours of training or have their M by October 1, 1997.

MS. KAUFMAN: And be a practicing.

MS. HEINLEIN: And be a practicing technologist.

MS. KAUFMAN: Yes. Mammo technologist.

MS. HEINLEIN: Mammo technologist.

Ed?

DR. HENDRICK: Yes. There needs to be some inclusion about having performed actual exams, whether it is being practicing or having performed a certain number of exams by that time.

MS. HEINLEIN: Would you suggest the same number of 50 exams by that time?

DR. HENDRICK: At least, yes.

MS. HEINLEIN: Okay. So it seems that the suggestion to the FDA for grandfathering is that they would either have their M and performed a minimum of 50 exams under supervision or just have perform, just have perform 50 exams, or they have 40 hours of training and they have performed 50 exams. Is that an acceptable proposal to the committee?

[No response.]

MS. HEINLEIN: Okay. So we have taken care of the grandfathering. Any question from the Charlies on that?

MR. BAILEY: Just as a point of clarification, when you say M, are you saying only --

DR. PATTERSON: Please identify yourself or the record.

MR. BAILEY: Ed Bailey from California.

Are you saying just the M from ARRT? We have a separate exam and everything where we have quite a few techs who have an M that may not have an ARRT(M).

MS. HEINLEIN: That is an excellent point.

Any comments from the committee on that, that they have an advanced certification, that they have passed an advanced certification exam in mammography?

Dan?

DR. KOPANS: Well, that is what I was suggesting earlier is that if there are States that do have advanced certification. I would like to see advanced certification in all States, regardless of how they have their license, but I think if it is certainly an accepted test in the State, that would be reasonable.

MS. HEINLEIN: Any other comments on that?

[No response.]

MS. HEINLEIN: All right. So i t is an advanced certification exam in mammography. You all get the gist of that.

Joel?

DR. GRAY: I guess I would disagree with that because we have no control over the quality of the examination that may be performed in some States in the United States.

MS. HEINLEIN: Ruth?

MS. McBURNEY: Nor do we have any control over the ARRT(M) either, but either one, you are probably going to have met the 40 hours of training in order to take that.

MS. HEINLEIN: Dan?

DR. KOPANS: I have concerns, too, but I j ust point out, you have on control over what the 40 hours of training are either. Someone pointed out, you could sleep for 40 hours and have an audio tape in the background.

MS. HEINLEIN: All right. So we are in general consensus here that it is advanced certification in mammography and performance of a minimum of 50 exams or 40 hours of training in mammography and performance of a minimum of 50 exams for grandfathering.

Elizabeth?

DR. PATTERSON: I think that advanced training in mammography needs to be qualified with those bodies certified or approved by the FDA. Otherwise, you and I can go out and say we are going to give an exam.

MS. HEINLEIN: Right. Any disagreement on that from the committee?

[No response.]

MS. HEINLEIN: I didn't think so.

All right. Now we are down to the next slide on (B), the performance of a minimum of 50 exams.

[Overhead.]

MS. HEINLEIN: There were 14 comments that supported this requirement. Seven said that there should be more. It needs to be specified that the exams are in addition to the 40 hours. New techs will need it, but not experienced people. Again, I think that was the grandfathering issue.

115 opposed the 50-exam requirement. Nine said that just the instruction is sufficient. Nine said that there were no qualified instructors based on the proposed final regs.

They did say that if there were, that would be fine, but since there was no one qualified, how could you require it.

Fourteen thought that the requirement had to be met under an M.D. and opposed it because they did not have one at their facility.

Twenty-nine said that it was not achievable due to cost, and that there was no qualified personnel. Again, I think a lot of these were making the comment based upon not grandfathering.

Two did not do supervised instruction because they said you shouldn't do it for patient privacy and for patient comfort.

Nineteen stated that rural facilities would have difficulty meeting the requirement. The difficulty in meeting that requirement was that they did not have enough patients for each technologist to have performed 50 under direct supervision unless they were grandfathered in. Again, I think this kind of goes back to the grandfathering issue.

Thirty-two just stated it would be difficult to achieve. One said the number should be reduced. Sixteen wanted the number higher. Fourteen said that it should be 100 exams. One said it should be at least 100 exams. One said it should be 200 exams, and one said we may want to consider attestation.

Again, I think that a lot of these comments came in thinking that there was no grandfathering, that every technologist would have to do 50 under direct supervision.

Are there any comments on whether we should suggest to the FDA any changes in (B)? According to the April changes, it would be that the performance of these exams would take place after they had completed their advanced certification or their 40 hours of training. Any

suggestions whether it should be deleted or whether we should just keep the -- let's go, first, should it be deleted or do we keep the 50 exams? This is new technologists for initial training.

We have one to keep. I hear a "keep" -- lots of "keeps." All right.

Any changes on making any recommendations as far as changing the number or keeping it at 50?

Carl?

DR. D'ORSI: Rita, do you want to have any further clarification of what a qualified individual is, qualified in maybe mammography, in technology? The way this reads, it could be an M.D. who is an interpreting physician, but has never done a mammogram in their entire life. Do you want to make that a little clearer, or is it unnecessary?

MS. HEINLEIN: Shall we state that this person shall meet the -- Ruth?

MS. McBURNEY: You can say qualified technologist, mammography technologist, or whatever.

DR. D'ORSI: There are some technologists who do mammography and they also read it. I would rather have the qualification on the technique rather than on naming a particular individual.

MS. HEINLEIN: Cass?

MS. KAUFMAN: You mig ht want to expand it, but there is a definition under (ii). A qualified individual is one who has met all of the requirements, paragraph (A)(ii).

MS. HEINLEIN: Elizabeth?

DR. PATTERSON: Yes. Why don't we let the FDA figure out the language and give them the concept.

MS. HEINLEIN: Any additional comments on the concept, then?

[No response.]

MS. HEINLEIN: All right. You get the gist.

Let's move on, then, to (iii), continuing education requirement. Did I skip one? Yes, training and implants. I'm sorry. (C), training and implants. That is the correct slide. You are right.

There were five comments that supported this requirement. They said you should also include imaging of five patients, and the other comment was that this should include doing patients, not just initial training, not just didactic education.

Fifteen said that if training is required that there is on need for an M.D. to be on site. That is a completely different issue that we will be addressing later on.

Many said that the 5 hours was excessive. Seventy-nine wrote in saying that you do not need as many hours. Sixty-four comments said you only need 2 hours. Two said 3 hours. Two people said 1 to 1-1/2 hours. Twenty-four people said only 1 hour. Twenty-five people said they only do a few a year. Eleven said this is just an impossible requirement to do 5 hours on rural areas, particularly if this includes doing what they thought would be five or six patients for each technologist. Many said that it just should be included in the initial training, without specifying the number of hours.

In addition to that, 26 people commented that it should be part of the initial training, and it just should show that they have had documented training, and imaging implants should be included in the positioning portion.

Some of the other comments on implants said that to require training is totally out of place. This is well covered in the "already" rules governing RT certification and continuing medical education.

Two comments stated t hat most experience and knowledge comes from performing the exam firsthand. Most RTs have been trained in implant positioning, but have not been given formal documentation. Adding this will place financial burden, as already required, because you are

already required to have 24 hours of continuing education every 2 years through the ARRT.

Another comment, training is important, but should be included in the original 40 hours, not in addition to that training.

Another one, RTs do need 5 hours of CEUs in implants. Any extra knowledge would only prove to benefit the patient and her resulting mammogram.

To the other end, it is too excessive to require implant imaging to make up one-third of 3-year average for CEUs. Instead, it should just state that each facility is required to determine the procedures to ensure patients with implants are imaged by a technologist who is properly trained.

Dan?

DR. KOPANS: I think that a requirement for 5 hours is overly excessive unless you are in California. There has been an inordinate stress on implants, and I think it is more important to stress high quality of mammography in the vast majority of women.

I would say include implant imaging in the training, but not give it 5 hours.

MS. HEINLEIN: Ruth?

MS. McBURNEY: Didn't Charlie just say that implant imaging was recommended to be added to the initial training?

MS. HEINLEIN: Right. We had said that in the April meeting.

MS. McBURNEY: Perhaps we could probably take it out specifically.

MS. HEINLEIN: Any other comments on that?

Yes.

MS. HAGERTY: Judy Hagerty from Mammography Accreditation Consultants.

As an implant patient as well as a mammography consultant, I have been to many, many sites. I teach mammography implant positioning, and I can tell you right now, the techs out there don't have enough training in this. They don't understand the implant patient. They are afraid of working on the implant patient. They are afraid of touching the breast because they are afraid they will rupture the implant.

I think this training is extremely important. I have done applications on 50 machines in the past year and have taught techs at all those sites on implants, and all of them needed the extra training on implant positioning. So, in my opinion, it is a very necessary thing. Whether it is

5 hours or not, at least one time in a tech's training, in her lifetime, she should have at least accumulated 5 hours in implant training. So that is my opinion.

MS. HEINLEIN: Amy?

MS. LANGER: Is there any video-based in struction available on this?

MS. HEINLEIN: Yes, there is.

MS. LANGER: Would that be appropriate for at least part of this requirement?

MS. HEINLEIN: I know that there are two videos that are available, one method to position patients with implants and another one showing another method. Yes, I certainly think that would suffice to show people how to go about those steps.

Ed?

DR. HENDRICK: How long are the videos?

MS. HEINLEIN: One video is, I want to say, 45 to 50 minutes, something like that. The other video is an hour, but the imaging of implants is a portion of that video. So my guess is it might be 20 minutes of that.

Any other comments on that?

[No response.]

MS. HEINLEIN: So the feel is that they should show document to training in the imaging of patients with implants included in the initial training.

Moving on to continuing education requirement, the next slide.

[Overhead.]

MS. HEINLEIN: (A), this is showing that they have taught or completed at least 15 continuing education units related to mammography in the previous 3 years.

Seventeen comments supported the change to 15 CEUs in 3 years. I think they were looking at it as 5 every year. Two comments stated that the ARRT CEU requirements are sufficient, that we should not have to have this in addition.

One comment said having the M should excuse RTs from continuing education.

Nine comments said change it to 10 hours every 2 years, and then, they wanted the cycle to be the same as the ARRT.

One comment, 12 CEUs every year wit h specific number required in each subject.

Five comments, you should specify that they should be category A credit as opposed to category B which could be reading or in-services that are not previously approved.

One comment said credit should be limited to seminars by independent organizations or professional journals or departmental in-services.

Eight comments said 5 years is a financial burden for rural facilities. So, again, taking 5 a year or 15 every 3 years.

Are there any comments from the commi ttee on this? Do we want to make a change or keep this as have taught or completed at least 15 CEUs in the previous 3 years?

Marshal?

MS. OAKLEY: Rita, I have a question about the comment that it is a financial burden for rural facilities. I don't know cost. What are we talking about? I mean, is there a standard fee? Is it $25 or $50? Eight of them made that comment.

MS. HEINLEIN: I think the cost can vary. I have attended conferences where someone could get 5 hours of credit for $20 if it is given by a mammography society. Many areas have established mammography societies where they hold a monthly meeting one night and evening, and there is no fee.

You can also get 5 hours of credit each year through reading in professional journals.

Cass?

MS. KAUFMAN: I was going to mention, if you are a member of ASRT, they send you their magazine, and if you read the article and take the quiz at the end of the article, you get category A credits for doing that. So you can do it at home. You don't have to attend any professional course.

You have got to get 24 hours to keep your ARRT every 2 years, anyway. So all we are saying is that 10 of those have to be in mammography if you are going to do mammo.

MS. HEINLEIN: Joel?

DR. GRAY: I would like to raise a question regarding the 10 hours every 2 years and have that as part of the ARRT cycle. Is that a real advantage to the technologist? Is that something the FDA should consider? It would eliminate separate record-keeping, as I understand it, because the ARRT keeps track of those CEUs for you. Is that correct? No?

MS. HEINLEIN: ASRT does. If you are a member of the ASRT, then they will keep track of it.

My personal opinion is I do not know that changing it to 10 hours every 2 years gives you any kind of an advantage.

DR. GRAY: I am just trying to make it "people."

MS. HEINLEIN: Understood.

Cass, did you want to make a comment?

MS. KAUFMAN: Well, it actually makes it harder because now you have got 3 years to get 15 years. I mean, even though we like them to be spread out, you can get 15 hours over one weekend, every 3 years, the way it currently is. So it is actually easier for the technologist.

MS. HEINLEIN: All right. So it is general agreement that we keep (iii)(A) as it is.

(iii)(B), at least six of these continuing education credits shall be related to each modality used by the technologist. Interestingly enough, there were only two comments on this section.

One said it was great, and the other said it wasn't. One said it would be a problem in meeting as far as if they did Xerox or if they did stereo or digital because they were not available unless you could include the manufacturer representative giving them classes as fulfilling that requirement. Anything else on that one?

Elizabeth?

DR. PATTERSON: Charles wanted to backtrack to the one before, one of the comments that was made previously in the April meeting.

MS. HEINLEIN: All right. On this one? For this?

DR. FINDER: (iii), in the other meeting, you suggested that we delete "have taught" or "taught" and just have "completed." Is that changed now?

MS. HEINLEIN: Any comments or concerns on that?

In April, we said that we would delete that they have "taught," that they would have to "complete."

DR. FINDER: Right.

MS. HEINLEIN: Dan?

DR. KOPANS: For physicians, teaching is counted as CME credits. Is it the same with technologists?

MS. HEINLEIN: It is through ASRT, but you have to apply for it for yourself, and they will only give you credit for teaching that lecture one time. Say I went out and I taught basic positioning and I taught it 50 times this year, I could only get one credit for the 1 hour. So that is different.

Any comments from behind?

Yes.

MS. PENTECOST: Lisa Pentecost, State of Arkansas.

When I do talks through the ARRT, I get twice what my recipients receive. If they receive 1-1/2 hours for my lecture, I get three credits through ARRT, just once. Now, I don't repeat the talk. Is that not how it is for you?

MS. HEINLEIN: The fool that I am, I have never put in for it.

[Laughter.]

MS. HEINLEIN: It is not like I am teaching every weekend. You would think I would.

But you get credit for that just the one time. So, if you should repeat that talk, you don't get credit for it the second time you would teach it.

Yes. Charlie?

MR. SHOWALTER: I just would put on the floor, what does the committee think of that as a middle-ground position between what was proposed and what was recommended in April?

MS. HEINLEIN: Cass?

MS. KAUFMAN: Y es, I like it. I had mentioned in April that I always work much harder at preparing a course to present than actually taking a course. So I like that idea.

MS. HEINLEIN: Penny?

MS. BUTLER: I would like to say I agree with Cass.

MS. HEINLEIN: Any other comments?

Elizabeth.

DR. PATTERSON: The only thing I can see with this is that people always find the easy way of getting around it.

Today, my talk is going to be positioning of the right breast, and tomorrow, it is positioning of the -- you know what I am talking about. It is the change of title, and it has now turned into a different talk.

MS. HEINLEIN: Any other comments, one way or the other? I am sorry we don't have more technologists to give comment to that.

MS. KAUFMAN: We didn't discuss the issue of category A versus B.

MS. HEINLEIN: Oh, no, and we should do that.

Any other issues as far as this, whether Charlie's proposal about this should be sort of a middle-of-the-road?

Two say yes, three, four, five, six, seven. All right.

We probably should step back. Cass brought up a point that with the continuing education, we didn't specify category A versus category B. I don't think that has been specified in here.

There was five people who commented that it should specify category A and then the one comment saying seminars by independent organizations, journals, or departmental in-

services. All of these would be category A, also, as the departmental in-services would have to be approved ahead of time in order to be category A.

Yes. Ruth?

MS. McBURNEY: But then you have the financial burden problem, also. So I really don't think that we need to specify that it meet category A.

MS. HEINLEIN: Any other comments whether it should?

Cass.

MS. KAUFMAN: The journal articles are category A that you can read at home and take the test. The only thing I don't know is how many of them might be in mammography. That is the only thing that I don't know.

We have specified category I for the physicians, and I don't think we did for the medical physicists. It is not specified.

I guess I am not sure this is a real important issue because, if you are ARRT, 12 of them have to be in category A. So you are going to have to get at least that many for ARRT, but that doesn't mean they have to be in mammography.

MS. HEINLEIN: Ed?

DR. HENDRICK: The distinction is category B is reading a journal, but not taking a test on it? Is that the idea?

MS. HEINLEIN: And you can just write down on a piece of paper, "I read this journal."

DR. HENDRICK: T hat doesn't seem to count for much for me. It seems like they should be category A.

MS. HEINLEIN: Category A?

DR. KOPANS: Maybe write in that the facility has to pay for their registration.

MS. HEINLEIN: Right. Would you like to take that on, Flo?

[Laughter.]

MS. HEINLEIN: Just remember where that came from.

MS. KAUFMAN: The facility can deduct it from FDA licensing.

MS. HEINLEIN: It is getting better.

DR. FINDER: Do these courses have to be in Boston?

DR. PATTERSON: Or Philadelphia.

DR. FINDER: Just checking.

MS. HEINLEIN: So the proposal to the FDA is that the 15 continuing educations related to mammography shall be category A. Is everyone in agreement with that?

Ruth?

MS. McBURNEY: Since this is a regulation, we would need to define what category A is because not everybody is going to be ARRT or ASRT.

MS. HEINLEIN: Okay. You get the feel from all of that.

Charlie?

DR. FINDER: Yes, but it is a very good point because, even category I, there are various different definitions.

MS. HEINLEIN: We could get the definition of category A from the ASRT for technologists.

DR. FINDER: Right.

MS. HEINLEIN: I mean, is that the feel from the committee that the should be category A, or do we want to change this?

MS. KAUFMAN: I guess I am a little nervous about making all 15 hours have to be category A for those rural people, since I don't know what percentage of those articles, for example, are in mammography.

So I think I would feel more comfortable saying 10 of them had to be category A.

MS. HEINLEIN: Any comments on that?

Charlie, you get the feel that we are not sure about this category A business.

DR. FINDER: Right, okay.

MS. HEINLEIN: All right. I will leave it to the FDA.

Did we make a decision on the six CEUs in each modality used by the technologist? Again, as I said, there were only two comments. One thought it was great, and the other said it could be a difficulty unless they accepted training by the manufacturer representative.

Ruth?

MS. McBURNEY: The comm ent that concerns stereo and digital, that is not what we were talking about in here. We were just talking about xeromammography and film screen.

MS. HEINLEIN: Correct.

So we keep it the way it is, six CEU in each modality.

The next section is (C), requalification. Following any 3-year period in which the technologist fails to meet the CEU requirement, that they shall attain a sufficient number of CEUs in mammography to bring the total up to at least 15. At least six would have to be related to the modalities.

Only two people commented with that, and they said that they agreed with it. My assumption is that, since we got no negative comments, probably every just did plain agree with it.

Any other comments on that?

[No response.]

MS. HEINLEIN: Moving on to (D), before the technologist can independently perform examinations using modality other than those for which she has received training, she shall receive at least 8 hours of CEUs in the new modality.

Only three comments on that. One said that this would cause an undue hardship to having training in each modality. One said it would be difficult to meet unless the manufacturer's training counted, related that also to the previous one. One, again, said that stereo and Xerox training was hard to come by.

Do we want to make any changes or leave that as it is?

I look at this and say three people commented, and there were well over many, hundreds upon hundreds upon hundreds of comments that came in from the technologist. So I think the majority agreed with what this said.

DR. FINDER: I just want to bring up one other point. In our other discussions, we already took care of Xerox.

MS. HEINLEIN: Okay.

DR. FINDER: So it no longer exists.

MS. HEINLEIN: Yes, Bob.

DR. SMITH: Pull that back down to that first category.

The issue that was raised about 10 and 5 in order to meet some conjecture about difficulty in rural areas, I am a little concerned about setting a lower standard or the consideration of setting a lower standard on the basis of some conjecture that it might not be able to be met without a clear sense that it can't be met or what the compromise that the lower standard really might be.

The question of rural areas is something that comes up repeatedly and has over the years, but we still lack very clear data as to the level of burden for that group. It may be very real. On the other hand, it may be that it is just something that can be always thrown out as a way to minimize the reg.

MS. HEINLEIN: Are you saying that you feel that the continuing education should be specified as a percentage of them being in category A or that they should all be

category A? Because other than that, we haven't changed the regulation.

Flo?

DR. HOUN: Let me just point out that since it wasn't proposed as category A, that impact was not allowed to be commented upon.

MS. HEINLEIN: Oh, that is a good point.

Did you hear that?

DR. SMITH: Yes.

MS. HEINLEIN: Ed?

DR. HENDRICK: I think the difficulty might be that we are setting up a system where rural areas or just sites that don't want to pay to have their technologists get additional education will say, oh, just read this journal, here is a 10-year-old article you can read on positioning.

MS. HEINLEIN: That is a point because I think that, in many places, if they don't have to get the training or go out someplace to get additional training, then they won't.

DR. HENDRICK: Yes. I don't think we are necessarily doing the technologist a favor by setting easier criteria here.

MS. HEINLEIN: Cass ?

MS. KAUFMAN: I agree with you, Bob. That is a concern in always worrying about the rural facilities.

The only thing I can comment on is that when ARRT put in their continuing education requirement, there were a significant number of letters written by the rural technologists saying that it was going to be a real hardship for them, and I don't know how valid their complaints were, but they seem to be the main area where concerns were raised about their ability to get category A.

MS. HEINLEIN: Howeve r, it still went through that everyone has to have 24 hours every 2 years.

MS. KAUFMAN: Right.

MS. HEINLEIN: Penny?

MS. BUTLER: Currently, there is a requirement for continuing education, and the FDA is interpreting what continuing education is acceptable or not.

I would like to suggest that we continue to let that continue, but we let FDA do that interpretation and just put the numbers in.

MS. HEINLEIN: Esther?

MS. SCIAMMARELLA: I second Bob's comment. There are a lot of fantasies in rural health to try to upgrade the condition of community health in rural centers, and I think we need to push for good quality.

MS. HEINLEIN: Bob?

DR. SMITH: Just for the record, I think it is incumbent to live up to the goals of MQSA which is a common standard that all women can depend upon. Otherwise, we send a signal that if you are in rural areas, you can rely on a lower standard.

If it turns out that women in rural areas, technologists in rural areas are having a very difficult time assessing this kind of training, then it is important for the FDA to call upon the Centers for Disease Control and State health departments and the American Cancer Society and other organizations to make this training available so that women in rural areas don't have to settle for a potentially lower standard of mammography.

MS. HEINLEIN: I would also point out that there were eight comments concerning the financial burden for rural facilities, and twice as many comments supported the change to 15 hours every 3 years.

So is the consensus, then, that we keep it as it is right now and the FDA will determine the level of categories, et cetera?

Okay. Everybody all right with that?

So now we have done all of that. Now we are on to (iv), continuing experience requirement, and the next slide.

[Overhead.]

MS. HEINLEIN: Wait. The next slide, we are not on to that one. This is the one that said they had to have 8 hours of continuing education in the new modality. We are on (D).

Two comments said reduce it to five.

No, you ar e right. That slide was correct. I'm sorry.

Two comments said that 8 hours of continuing education in each modality should be reduced to five. Two supported the requirement, but documentation may be difficult or we may need to clarify on how to document.

Nine said reduce the hours, but gave no suggestion. One said it could be a burden, which is not compensated by higher pay.

One said excessive. One said let the facility decide how many hours they would need for continuing education in each modality. One said you may want to accept attestation. Three comments supported the requirement.

Dan?

DR. KOPANS: I'm sorry, Rita. You mentioned earlier that the new modality was zero radiography. Is that what you are calling new modality, or could it be ultrasound?

MS. HEINLEIN: Under these regulations, modality is only film screen or Xerox.

DR. KOPANS: You mean if you were doing Xerox and you were going to switch, then, to film screen, you would have to meet this requirement and vice versa?

MS. HEIN LEIN: Yes.

DR. KOPANS: I don't think anyone is switching to Xerox.

MS. HEINLEIN: Right.

DR. KOPANS: New modality is very confusing. I thought it was ultrasound, for example.

MS. HEINLEIN: Ed?

DR. HENDRICK: I think the intention is when full-field digital becomes clinically available, that would be the best example. I mean, most people would be adding that to the film screen capabilities they have.

DR. KOPANS: Maybe just clarify new modality. Is it written somewhere? I'm sorry. I didn't see it.

MS. HEINLEIN: It is in the definitions.

DR. KOPANS: It is?

MS. KAUFMAN: It is also supposed to include stereotactic because that, most likely, is going to come under this at some point in the future. These regulations presumably will be around for a while.

DR. FINDER: They will have their own regulations. It will be a separate document.

MS. KAUFMAN: This won't apply to that?

DR. FINDER: What we are thinking at this point is that it is basically for digital, and we assume that we are going to have other regulations for stereotactic.

MS. KAUFMAN: Oh, okay.

MS. HEINLEIN: Any other comments on the 8 hours of training in each modality?

DR. HENDRICK: I guess I would just raise the question. For a technologist whose experience is positioning in film screen, do you need 8 hours of additional training in full-field digital to operate while in that new modality?

MS. HEINLEIN: Dan?

DR. KOPANS: There aren't too many of us who have had experience with that, but in our experience, no, that is not really 8 hours that is needed.

The mammographic positioning -- well, I should say it will depend on the type of system, but that is more learning which buttons to push as opposed to the actual performance of the mammogram, which is identical, pretty much, to conventional mammography. I don't think you need that many hours for full-field digital.

DR. HENDRICK: You have to include the pushing of the buttons and the taking of the films and all of that.

DR. KOPANS: I don't know. Some of the other systems may take longer for all I know. I don't know.

DR. HENDRICK: So we don't know.

MS. HEINLEIN: Elizabeth?

DR. PATTERSON: Yes. I think this was sort of left open-ended under that new modality for anything else that came down the pike by the time these things really got into regulations and not have to redo, be it digital or whatever other modality that Dan or Larry or Carl was going to create within the next 5 or 10 years.

MS. HEINLEIN: Dan?

DR. KOPANS: New modality in here, that stereotactic is not going to be under this, then you really need to define very carefully what new modality is, it would seem to me. Is it digital full-field with an area detector, with a scanner? I think anything that is X-ray imaging of the breast, I am surprised and it should be under this. I am surprised that stereotactic would be separated out.

MS. HEINLEIN: Carl?

DR. D'ORSI: Until definitions for this? Because this is going to be covered under there.

MS. HEINLEIN: Okay.

DR. D'ORSI: Ad nauseam.

MS. HEI NLEIN: All right. So we are ready to move on, then, since we are going to cover new modality under definitions.

So we leave this as it is? All right.

Let's move on to (iv) which is the last section, and that is continuing experience requirement.

[Overhead.]

MS. HEINLEIN: What is interesting to me, nine comments supported this requirement, and the requirement is they would have to perform a minimum of 100 exams per year for continued experience.

Nine supported it, said you need to perform mammograms in order to keep your skills up. More mammograms equal better positioning skills. Very acceptable requirement.

Two comments, actually, argued for a higher number. One said you should do at least 200 exams per year, are needed to maintain your skills. One said it should be the same as the interpreting M.D., an average of 40 per month averaged over 2 years.

Four comments supported the 100 exams, but wanted a longer averaging time, averaging 100 per year for 3 years or 200 over 2 years. They said the reason for that would be

so that technologists would be able to take an extended leave or maternity leave, et cetera.

Six comments opposed the requirement. They said there is no need for a minimum quote. If you can do a mammogram, you can do it, period.

[Laughter.]

MS. HEINLEIN: Two people said every 3 years, there should be a competency certification, like the CPR certification.

Twelve comments felt that this would be difficult for the rural area to meet the requirement. In fact, one said that they did only 166 mammograms last year. They have two RTs. They could not keep both qualified at 100 exams for each one. One said you may never perform 100 exams per year, and you would always be playing catchup.

Thirteen comments felt that mammography supervisors, nonpracticing RTs, RTs rotating to other services, RTs on extended leave would have a hard time meeting this requirement, and I know there have been other comments. I don't know that they were written in, the business industry and manufacturer representative saying what if I wanted to get back into mammo, I wouldn't meet this qualification.

Two comments cited that they only have part-time people. So it would be hard for each one of them to meet 100. Five comments said that 100 a year is too much. Mammography is "not that more demanding than any other highly-skilled exams we perform."

Six said 50 per year. One said 75 per year. Other comments went on to say this will put undue strain on facilities that do quality mammography, but have a limited number of patients.

Many people took the route of averaging over a longer period of time, like the M.D., so as not to penalize RTs who take an extended leave.

One person said to insist that an RT do a certain number of exams to keep her certification is ludicrous, and it eliminates people working as teachers and sales persons. If I have been initially trained, I have passed the registry. I have taken CEUs, and I teach positioning daily. Why is it necessary to expose a certain number of films? Numbers prove nothing. So there was a wide range of this.

Many of the comments talked about extending it, averaging it like 200 over 2 years or 300 over 3 years, so that those that were part time and filled in for vacations or whatever would have an easier time meeting the requirement. Extended leave people would have an easier

time. Part-time people would have an easier time. That may also make it easier for the people that were highlighted here as far as sales people or anything like that.

Are there a ny comments on that?

Carl?

DR. D'ORSI: I think if we give that provision to the radiologists, that they are allowed to accumulate this material over 2 years or the reading over 2 years, I think that should also be accorded to the technologists, if we buy off on the 100 or 100 per year as adequate. I mean, if that is established, like theoretically the 480 is, then we should give them a longer period for vacation, maternity leave, whatever.

MS. HEINLEIN: Any other additional comments to that?

Ed?

DR. HENDRICK: I agree.

MS. HEINLEIN: Ed agrees with that.

[Affirmative responses.]

MS. HEINLEIN: Is the suggestion to go an average of 100 per year, averaged over -- shall we do 3 years, the same as the physician, or 2 years -- I'm sorry -- 2 years, the same as the physician?

[Affirmative responses.]

MS. HEINLEIN: Cass?

MS. KAUFMAN: My only concern is the 100 exams because it would seem like we got an awful lot of comments from people saying that was too many, and I don't know the answer to is, but I would certainly be willing to consider a reduced number.

MS. HEINLEIN: Marsha?

MS. OAKLEY: I would like to see it stay at 100, and I kind of agree with what Bob said earlier. If they are really having trouble, there are places or organizations, institutions in the State that they can make that appeal to.

I am just afraid that if we loosen it, there will be somebody who is looking for a loophole and be right there.

MS. HEINLEIN: I think we also came up with that number averaging that that would only be an average of two mammograms a week.

Ruth?

MS. McBURNEY: There is a consideration, though, for those low-volume facilities, and you have got several comments from those that, among 2 RTs, they only did 166 mammograms. So I do think that we need to make some concession, just because otherwise we are going to disallow some access.

MS. HEINLEIN: Gilda?

DR. CARDENOSA: Going back to Bob's earlier comment, I think the goal here is quality mammography. From somebody who has got some rural sites, I can tell you that he techs that do the least number have, by far and away, the poor positioning, and I really believe that you have to limit the number of people so that you are concentrated.

Yes, it creates other problems, but if we are trying to improve quality, then I feel pretty strongly that 100 is a minimum, and I actually think it should be higher.

DR. KOPANS: I actually would suggest that, although I don't know what we are going to do. I don't understand how a facility could do 160 mammograms a year, pay for the equipment, and keep their processor up. I mean, it seems to me that the whole quality, the quality of the program would suffer, but I don't think I would reduce the requirement.

MS. HEINLEIN: Carl?

DR. D'ORSI: This goes back to the discussion for the 480 exams, and if you feel that 100 is correct, for whatever reason, then you shouldn't make exceptions and that should be the rule. That is the whole idea of these regulations, to get some kind of a minimum.

MS. HEINLEIN: Joel?

DR. GRAY: I agree with the 100 figure. I think if you are doing less than that, I would question whether you should be doing mammography at all.

MS. HEINLEIN: Ruth?

MS. McBURNEY: The difference between a tech doing 100 a year and a physician reading 480 or whatever is that they can double-read. Whereas, the tech actually has to have that patient there to examine.

MS. HEINLEIN: So, if they double-read, that would be, what, 240 that they would be reading?

MS. McBURNEY: No. I meant that the physicians can read other physicians' films and so forth.

MS. HEINLEIN: Right, okay.

Cass?

MS. McBURNEY: To meet the requirement.

MS. KAUFMAN: I guess the 100 number was arbitrary. I mean, we don't really have any data on what number you need to do to be able to stay proficient.

MS. SCIAMMARELLA: We discussed that.

MS. KAUFMAN: But we got an awful lot of comments from people who didn't think that it needed to be that high.

It isn't just rural areas. There are lower volumes.

MS. HEINLEIN: And not only low volume, but the other problem is that many facilities -- and I personally disagree with this -- they will have every female technologist rotating in doing mammography and have gotten complaint comments from them, too, saying I can't rotate to other areas if I am going to make sure I get 100.

Bob?

DR. SMITH: I think we are all going back and forth across two perspectives right now, but a lot of our guidance this committee gives is based upon expertise and expert judgments in the absence of clear data. There are many other categories that we have that we don't have gold standard or even nickel standard data to support, really, what we are trying to do here.

The point is that this rule, if you compromise it, what you are doing more is protecting somebody's right to do mammography in the guise of making sure that if service if available in rural areas.

It is a more compelling issue if you can say in this facility, women would have to drive 9 hours in order to get a mammogram, and this rule would essentially eliminate mammography for them because these technologists can't reach this requirement this way. That is the context in which to

consider this as a problem, and we haven't been presented with that context.

What we have is a situation right now that says I can't meet that requirement because of the situation you have just mentioned where you have got 15 techs doing a little bit of mammography or you have got two people sharing the load that don't necessarily have to. I am really not at all in favor of cutting this limit back.

MS. HEINLEIN: My personal opinion, I am not in favor of cutting it back either.

I have been to places where they say, "Oh, I am so excited. I get to be here for the next 2 weeks so that I can make my 100 number," because many places think that is already in effect.

Charlie?

DR. FINDER: I just want to bring up this point because it was brought up to me by a facility that asked this question, and I thought it might be appropriate to bring it here.

What about two techs doing the same patient, one each side?

MS. HEINLEIN: That is a good point. That came up in one of the letters. One of the letters said that the tech should not be able to count that as an exam that they

have done. If two people go in and you do one side and I'll do one side, that should not count as a whole exam. It should even count as either a half exam for each. So there were comments that did come in on that.

DR. FINDER: Right, but then, what do we do about the unilateral mammogram patient or the mastectomy patient? Is that an exam or not?

MS. HEINLEIN: Right.

DR. FINDER: These were the questions that were asked of me, and I kind of said I would bring it up here.

MS. HEINLEIN: Okay, thank you.

[Laughter.]

MS. HEINLEIN: Dan?

DR. KOPANS: Quite frankly, I wouldn't have a major problem with that. I mean, if one of the techs is qualified, you do 50 cases with her, you actually fulfill your requirement with fewer cases. So I don't see one breast versus the other.

I am surprised and I am embar rassed that I don't know whether FDA asks how many cases a year each of our facilities does, but you should have some idea, I would think, or if you don't, you should be asking it. How many of the facilities really might even have this problem?

What I would like to see is that this is the standard and then a group can appeal to FDA for some kind of dispensation as opposed to lowering the whole standard.

MS. HEINLEIN: What is the requirement? Doesn't the State of Massachusetts have a requirement for technologists that they perform so many? Wasn't it like when it first came out something like 1,200 exams?

DR. D'ORSI: It was 1,460 hours -- hours, not exams -- hours of mammography, and there was a revolution. They cut it back, I think, to a couple of hundred hours now, 200 hours. It is hours, not studies. So it is probably much more than 100 mammograms.

MS. HEINLEIN: Yes. Joel?

DR. GRAY: I think we have gotten to the point where we are sort of debating how many angels can dance on the head of a pin.

DR. D'ORSI: 200.

MS. HEINLEIN: So can I assume that the consensus is that we keep it at 100, but we average 100 per year averaged over 2 years? Is everyone all right with the averaging?

[Affirmative responses.]

MS. HEINLEIN: Okay, all right. Let's go on to the last section, and that is (iv)(B), requalification.

That states that any 12-month period in which they fail to perform at least 100 mammo exams that they shall perform a minimum of 50 under the direct supervision of a qualified technologist before resuming performance independently.

There were only 13 comments on this, and quite frankly, I was surprised at that. I thought there would be many more, but there weren't more. I mean, when you consider the fact that there were six binders of comments concerning the technologist qualifications, only 13 made comment on this.

Three said that requalification would increase cost or be logically difficult. It would increase cost because they would have to have two people in there, one supervising while the other person did the exam, and it would be logically difficult because if they didn't have a large number of female -- of qualified technologists that some of them would have to be taken away to observe while the other person positioned these 50.

One said 50 was excessive, and that was pretty much the gist.

Two said 30 would be sufficient.

One said 25.

One said 20.

One said give a proficiency test instead of 50 exams.

Two said 50 exams are too many.

One said the requirement is very good a nd that it can be met through regional seminars, except who would maintain the records. That was the question, who would maintain the records.

One comment believed that there should be a penalty for RTs if they do not meet the 100-year experience. I don't think they realized that this was the penalty that they didn't receive it.

So maybe I should say 12 valid comments came in.

Ed?

DR. HENDRICK: We have just modified the previous clause to say 100 per year over a 2-year period. So you don't necessarily fail now if you don't do 100 exams in any 12-month period.

MS. HEINLEIN: Right. So that would have to be modified, also. Okay, they already got that.

Since that modification has taken place, do we just want to keep this stated, then, the way it is, 50 exams under direct supervision? Any comments thinking that should be changed?

I mean, I know that some of the comments that were made this morning said this is a large number, 12 or 13, but when I take a look at six big binders of comments on technologist qualifications, I guess I saw 13 as not very many.

Ed?

DR. HENDRICK: Can we revisit the grandfathering issue just for a second? When you asked what was the minimum number of examinations to be performed to meet the grandfathering criterion, we said a minimum of 50, but to be consistent with this, it sounds like we ought to say at least 100. I mean, the spirit is at least 100 exams on your own or 50 under the supervision of someone who is qualified.

MS. HEINLEIN: Any additional comment to that? Under the grandfathering clause, it would be that you have advanced certification in mammography or have 40 hours of training and have performed, Ed is now saying, a minimum of 100 exams within the last year or within the last 2 years.

DR. HENDRICK: I didn't intend to specify the last year, but you may want to say within the last -- I don't know -- 2 or 3 years.

MS. HEINLEIN: Right. These would be the people who would be grandfathered in.

DR. KOPANS: I would be careful with "ever" because there are maybe people who did mammography 10 years ago.

DR. HENDRICK: I mean, maybe you want to say at least 100 a year over the last 2 years or something like that. I would defer to the technologists on this, but I do think it should be consistent.

MS. HEINLEIN: Well, since I am it. I am sorry there isn't another one.

Marsha?

MS. OAKLEY: I am not a technologist, but I will support you on the consumer end of it. I would like to not see it be something that is too far back. Two years to me seems reasonable, not beyond that. So I really would like to not have it be out too far.

MS. HEINLEIN: Elizabeth?

DR. PATTERSON: As the technology has changed over the course of years, I would hate to have it way back. I mean, I can remember, gray hair in the midst of that, when they were doing them tabletop.

MS. HEINLEIN: Right.

DR. PATTERSON: So I would hate for somebody to come in and say, "Oh, this is a dedicated unit?"

MS. HEINLEIN: Shall we say, then, that they have performed 100 exams? An average of 100 exams per year over the past 2 years. Okay. Is that all right? Do you have all that?

A comment? Yes.

MS. HAGERTY: I am Judy Hagerty from the Mammography Accreditation Consultants.

Just in this whole thing in general, I am a little confused. Where do the mammography applications and the mammography sales people fall in all of this? I mean, are we required to meet the same requirements as the technologist?

MS. HEINLEIN: Dan?

DR. KOPANS: I would suggest if you are going to do mammography, yes.

DR. PATTERSON: If you expose the films, then you are going to have to meet the requirements.

MS. HAGERTY: Judy Hagerty from Mammography Accreditation Consultants again.

My question was, if you are teaching people to use the equipment or you are demonstrating the equipment to people, do you have to meet the same requirements. If you are not exposing the films because most applications and most sales people are not allowed to take the exposures, the

techs have to take the exposures. The techs do the positioning. We just demonstrate and teach them how to use and we supervise them while we are using the equipment. Do we have to meet these same standards? In other words, how do we get our 100 patients over 2 years is what my question is.

MS. HEINLEIN: Marsha?

MS. OAKLEY: My small piece of the world. My understanding when I saw people, like you, would be coming in to work with the tech, if you are teaching the tech how to do this, are you not with her, with a patient, doing it at the same time? To me, that qualifies you if you are in there and with a patient.

If you are teaching her how to place this woman on a plate, are you not also doing it yourself?

MS. HEINLEIN: I'm doing it.

Dan?

DR. KOPANS: I am misunderstanding the question. As an applications person, I don't think FDA has any requirements for application persons. Maybe I am wrong about that.

DR. HOUN: We just had our training requirement. We just had a training requirement that says in order to do the 40 hours, which I think she is going in trying to train

to meet the 40-hour requirement, they have to be done by a qualified individual that you are saying would have to meet these requirements.

DR. KOPANS: What I would interpret it as is if your company has sold a piece of equipment and you are going in to show how it is used, you don't need to meet these requirements, but the people who are listening to you don't get credit for you teaching. You are just showing how to use the machine, but if you want to teach and they get credit for the 40 hours, then you have to be qualified, and I think to be qualified, you have to fulfill all of these requirements.

MS. HAGERTY: If we meet the requirements where we have our M and we have been previously a mammography technologist and we have done well over 100 and we keep up our continuing education credits, how do we keep up our 100 patients over a 2-year period is my only question. I mean, do we have to go outside of applications and work in a facility in order to get our 200 credits, or does the time that we are working with techs on actual patients count? We need some clarification.

MS. HEINLEIN: All right, thank you.

I think that is an issue that the FDA needs to address. I know that comment will come up from applications

specialists, from the equipment manufacturers. If the committee has any comments on that, we can certainly share them with the FDA.

Ed?

DR. HENDRICK: I just have an additional confusion. If a radiologist or a physicist contributes to the educational program of the technologist, don't they qualify as qualified individuals to teach some of these 40 hours?

MS. HEINLEIN: They do. Don't they, Charlie?

MR. SHOWALTER: Well, indeed, and that is the problem with saying that only technologists can be qualified as people who instruct.

Indeed, it may be that people who are not qualified at all under MQSA or teaching biology or some other relevant subject, and I wouldn't want to discount that personally.

DR. HENDRICK: Right. So that has implications for the question that she asked in that, that person could be qualified to teach some of the 40 hours. They may not be qualified to supervise the positioning of the 50 patients that would be required to get that person qualified themselves.

MS. HEINLEIN: Flo has just pointed out that that refers back to (ii) on page 14907 under (B) for the general. Again, that goes back to them meeting that qualification.

MR. SHOWALTER: I do think the issue that was raised is an important issue. I think there are a lot of otherwise qualified technologists who do consulting or work for equipment companies, do applications. If the committee has any advice on this subject, I think we would appreciate hearing it.

MS. HEINLEIN: Cass?

MS. KAUFMAN: Always being reluctant to give advice, my suggestion would be, as long as they meet all of the other requirements for a mammography technologist, that they ought to be able to count those examinations that they are providing instruction on either in terms of application or positioning as meeting their 100, even though they are not actually pushing the button. They are certainly providing supervision and oversight to the examination, and the person who is receiving the training cannot count those towards their 100.

MS. HEINLEIN: That is a good suggestion.

DR. PATTERSON: But they would have to meet the initial qualifications.

MS. HEINLEIN: Right, yes.

Any disagreement with that?

[No response.]

MS. HEINLEIN: Okay. Thanks, Cass.

Penny?

MS. BUTLER: What about the requirement that tec hs do so many under direct supervision? That would mean the person receiving the instruction couldn't count that they were being directly supervised?

MS. HEINLEIN: No. They could count that as being directly supervised. That would go in their direct supervision count, but it would not go in their 100-per-year-averaged-over-2-year count. Right.

Joel?

DR. GRAY: I guess I really don't see a problem with counting, if you will. I don't see why the instructor can't get credit and the student can't get credit because we have said with the radiologists, they can get credit if they teach something and the students can't.

MS. HEINLEIN: They double-read?

DR. GRAY: Well, they double-read, too, but that is a little different. That is an independent, usually.

MS. HEINLEIN: All right. Any comments on if you have someone instructing that they both be able to count that to do a double count?

Cass?

MS. KAUFMAN: Yes. I think it is different because of the double reading they do independently. In this particular case, you really have someone instructing someone else, and I don't think the student ought to be able to take credit for that as an independent examination.

MS. HEINLEIN: That is a good point.

Yes. Carl?

DR. D'ORSI: I just need some guidance from the technologists. Is it the same if an application specialist basically looks at, let's say, 5 years worth of exams and then decides to do mammography? Is that really equivalent to actually doing the exam, looking at the films, evaluating compression, evaluating artifacts, evaluating penetration, evaluating position? Are you satisfied with that? That is all I am getting at.

MS. HEINLEIN: I don't know that that is the only thing they are doing. If you are going in to teach someone how to use the equipment, they are actually in there with the patient and helping them do the position itself. I don't think it is only this is push the button and this is look at the film that the button produces.

DR. D'ORSI: I understand that when somebody who is teaching technologists, particularly positioning, that

they do evaluate everything. I have no problem with that, but if they are in there with a particular machine just training on how to use that machine, I may be wrong, but I am just a little worried that if they do this for 10 years and then decide tomorrow to go out and do clinical mammography that they will have met the requirements for doing the exam.

Now, I don't know if that is a valid worry or if it is just not valid.

MS. HEINLEIN: Dan?

DR. KOPANS: I think qualification to do a mammogram should be qualification without exception.

To sort of reinforce what I think what Carl was saying, you can be an applications person for 10 years, never actually do a mammogram or see the resulting, even, of your teaching if you are teaching without actually exposing the mammogram and be totally doing it incorrectly.

So I would say that to maintain your qualification to do mammography, everyone should have to do the same thing. The interpreting radiologist, we look. That is maintaining our qualification. We use our eyes, and if you have two people using your eyes, you are actually doing two separate studies, if you will. So I think that applications individuals can teach how to use a machine, but if they are

going to be qualified as teachers and qualified as mammography technologists, they need to keep up their skills.

MS. HEINLEIN: To do patients.

DR. KOPANS: Sure.

MS. HEINLEIN: Cass?

MS. KAUFMAN: My comment was based on them doing patients, and generally, it is my understanding that during applications, they do, do patients.

MS. HEINLEIN: I think that can vary form company to company. I think that there are some companies that tell their applications specialists that they can go in and teach how to do the buttons.

MS. KAUFMAN: Yes. What I am talking about is shooting patients.

MS. HEINLEIN: Right.

MS. KAUFMAN: You have to have shot patients.

MS. HEINLEIN: Exposed.

MS. KAUFMAN: Exposed patients.

[Laughter.]

MS. HEINLEIN: Roland?

MR. FLETCHER: I think we may be being a little inconsistent here. We just had a conversation about two technicians going in to the same patient -- or

technologists. I'm sorry. -- going in to the same patient and we only give 50 percent to each, but now we are talking about a teacher student situation where we are willing to give full credit to each.

MS. HEINLEIN: Full credit to the teacher if she was teaching positioning and did the patient, but not full credit to the student. The student, because they are not independently performing it, could not count that in their independent performance count.

Ed?

DR. HENDRICK: Now I do think we have reached the angels dancing on the head of the pin.

[Laughter.]

MS. HEINLEIN: All right. I think you get the gist of all of this.

Let's just go to the last two. I just want to make sure that we have answered the questions that the FDA has posed in their questionnaire. Is there something else?

DR. FINDER: Actually, I did look through when you did get through the questions.

MS. HEINLEIN: Oh, we did? Okay, good. So you are happy with all of that.

DR. FINDER: You did have the retention issue still to discuss.

MS. HEINLEIN: All right. We are okay? You have looked through these and we have covered all of the questions.

DR. PATTERSON: Yes. You covered all of it.

MS. HEINLEIN: All right. Well, do you want me to do something quick on the retention of records? There is only one thing.

DR. PATTERSON: Yes. You need to do the retention of records, which is 14908, and it is one paragraph. We ought to be able to do that.

MS. HEINLEIN: If I could just take the next hour to do this one paragraph on 14908.

All right. You know what slide that one is.

[Overhead.]

MS. HEINLEIN: All right. There were only 21 comments on the retention of records. Four said that it is important to require a retention of records for previous employees.

Three said that the records must be available for the MQSA inspector, and you shall not discard them until FDA has determined that the facility is in compliance. At that point, if you are in compliance, they felt that you should be able to get rid of the records.

Four said that you should always keep the initial qualifications while the person is employed.

Four said continuing education and experience requirement, again, you should just keep for the current averaging period and the inspection. Once you have qualified, you can discard them.

Two said to allow the records to stay at one site; that if they had multiple mammography sites, it would be advantageous if all the records could be at one site for the inspection at one place, instead of having to ship records and make copies and make sure they are available at different places.

One said keep the initial requirement records forever.

One said keeping these records is an unnecessary burden.

As it states right here, right now, they are just saying they must be available for review by the inspector and that they shall not be discarded until the next annual inspection has been completed and that the FDA has determined that the facility is in compliance. I think many of these just support what that says.

Any comments? Any changes? Keep it the way it is?

Joel?

DR. GRAY: I hate to say this, but the physicist is not included in this, and yet, the MQSA inspector expects to see the physicist's records at each site.

MS. HEINLEIN: But it says of all personnel employed by the facility and the production processing and interpretation. It doesn't say in the evaluation of.

DR. GRAY: Just as a clarification, this is section (4)(i)(ii)(iii) were the three types of personnel. So this section is intended to apply to all of the above personnel, the interpreting physicians, the medical physicists, and the radiologic technologists.

MS. HEINLEIN: Penny?

MS. BUTLER: Maybe the word "employ," then, is incorrect if you are not working on a contractual basis, as many physicists area.

DR. GRAY: Why don't we just say physicists, technologists, and radiologists.

MR. SHOWALTER: Interp reting physician.

DR. GRAY: Whatever.

MS. HEINLEIN: Cass?

MS. KAUFMAN: It does include more than that because we have said that qualified people, for example, can do the densitometry and sensorimetry, but they have to be

properly trained. So you might have to have records for those people.

DR. HENDRICK: You could just add that personnel employed or contracted to do the things listed, plus quality control.

MS. HEINLEIN: Right. You get the feel of that.

Any other comments? Charlie?

DR. FINDER : I just want to go back. In terms of the questions, I think we have gone through and answered these, but maybe it would pay to just get a simple yes or no on some.

MS. HEINLEIN: All right. Well, we do have overheads on them. If you want to put those other two overheads up, we can run through them very quickly.

DR. FINDER: Oh, you do?

MS. HEINLEIN: Yes. I made overheads of them.

DR. FINDER: It is really the first two, I think, that we could get a little bit more specific on.

MS. HEINLEIN: Oka y. Several comments stated that setting arbitrary requirements for initial training and for continuing numbers of CMEs or mammograms performed is merely bureaucratic. Does the committee feel at the present time that a performance-based standard could be used to replace these requirements? For example, should the FDA increase

accreditation bodies, CIR, as a means to check technologist performance? If so, what should that be increased to?

I say keep it the way we have it right now. Any change?

[No response.]

MS. HEINLEIN: All right. Number two, should requirements for technologists implant imaging apply to all technologists or just those performing examinations on examinees with implants.

There is such a large comment on implants. I mean, I don't know if you want to hold that until we get to the end because a lot of those people made comments in that regard.

Number three, should a specific number of hours of training in the imaging of examinees with implants be required? We have already taken care of that.

Should the nature of training be specified? Should videotapes be allowed? I think we have talked about that. Amy brought that up.

For what requirements and under what conditions would it be appropriate to grandfather? We have certainly talked about that.

Additional topics be added, we took care of that.

The division of opinion on the committee, does the committee have any additional advice on initial experience? I think we have answered all of these.

Definition of individuals qualified t o provide instruction, should it be written? I think we alluded to that, and you said that the FDA would run with that.

Should the time periods for evaluating continuing experience be defined in a more flexible manner? I think we have done that.

I would like to put on the record a hearty thanks to the many, many, many technologists that wrote in, and I can't tell you how happy it will be to read something other than these letters.

[Laughter.]

DR. PATTERSON: Thank you, Rita.

It is a quarter of 4:00. Let's take a 10-minute break and then come back promptly so we can continue on.

[Break.]

Interpreting Physicians

DR. PATTERSON: I would like to continue on with the agenda. We are now up to 9:00 a.m. this morning, and we are going to go on to interpreting physician. After 3 years, I get an opportunity to talk.

[Overhead.]

DR. PATTERSON: This is on the interpreting physician. I guess we will start off with the most frequent comment, and some of the letters were quite elaborate in this, but there was over 115 of them that said the term "interpreting physician" should not be there, it should be radiologist. There are at least seven of us in this room that agree with that, but that is besides the point.

That was a very common comment not only from radiologists, from physicists, and the consumers. I think there were probably as many from consumers as from the radiologists.

As far as initial qualifications -- oh, I'm sorry. I should have told you we are talking about pages 14907, and we are on (1) and down under (i).

Under (A), again, the terminology about licensed in the State was used, and these were probably the same individuals that sent it in regarding the technologists, but there were a number of those comments.

A number of them were form letters, the ones that were Xeroxed off and sent in.

The certified, there was about, oh, 49, 50 letters stating that this should only be a board-certified individual. Some of them used "certified." Some of them

said "board." It is amazing how many individuals confuse the term.

The ACR and ABR, but they wanted them ACR-certified, this confusion.

Then, there were some that were against board certification, and there was one that went into very long detail on why they were against it. Some of the comments were quite valid. They made the comment that prior to '89, individuals had not been either trained or examined in mammography that were boarded, and then they went into, well, this is all a personal and subjective type of thing, and it depends on how your personality clashes with the examiner, that type of thing.

Then, there was the one comment that talked about the class A rule. I am curious. Are there any of the radiologists who knew about the class A rule?

You looked it up, too. Well, this individual cited an article in the "Illustrated History of Radiology" by Eisenberg, et cetera, and talked about the class A rule, which were individuals that were given the board certification without having taken an examination, and he referred back to this particular article which I happen to get. I actually made some copies for some of the radiologists that were interested in this, but basically,

when the board started, the ABR started, back in 1934, as you got together to decide who was going to be boarded, they had to have somebody who was going to examine them.

So they said, "Okay. Those of you that are teaching radiology in major institutions and universities, et cetera, would be given 'the class A' and you would be the examiners and you wouldn't be examined." So they basically gave them the certification.

I am assuming these were like the Hodis and the Pendergasts. I don't know of too many individuals who were boarded in 1934 who are still practicing now. There may be. This was his major objection to the class A rule and so for the board certification.

The other comment about the initial qualifications was on the 3-month document, formal training, and some of them said that 3 months was not acceptable. They only needed to be board-certified. I mean, we had pros and cons on that.

Some of them said you had to have a full 3 months of training or you had to specify the number of hours that would be included in this formal training.

Some of them felt that for anyone who was doing mammography for a long period of time only needed 2 months of training, and they sort of excluded the exception which

we will get to a little bit later, which is basically those that have been certified under the interim rules. They didn't realize that that existed.

There was the physics requirement that was questioned by several. They felt that they should require a certain number of hours. There also were some who asked questions on who was qualified to give the physics, and then there were others that said only physicists could give the physics to meet this requirement. Those weren't all by physicists that made that comment.

The other ones as far as the documented formal training, there were questions about who would be qualified to give this training. Some of them said it shouldn't be another interpreting physician, but it should be only somebody who was qualified to give CME, like in a residency program. Some of them said any residency director, even though they didn't meet the qualifications of an interpreting physician for mammography.

Then, there was also the final comment about this, what did direct supervision mean, and they felt that that should be clarified a little bit more on that.

I thought I would stop at this point and ask are there any questions or comments that the committee is feeling regarding the initial qualifications.

[No response.]

DR. PATTERSON: None?

Yes. Cass.

MS. KAUFMAN: FDA had a bunch of questions relative to the 3 months of training that I am not sure we have addressed. Some of those were, should all 3 months of physician training be obtained in an approved residency program or can it be taught by someone who currently teaches mammo in a residency program or can it be given by someone who at one time taught mammo in a residency program or can it be obtained from any interpreting physician.

DR. PATTERSON: Okay.

MS. KAUFMAN: I don't think we answered that.

DR. PATTERSON: No. I had the questions at the end, but that is okay. That is all right. If you want to go in and discuss them as we go along, I don't care.

MS. KAUFMAN: Okay.

DR. PATTERSON: Let's go sort of in order on this. I don't know how you want to. I think addressing "the State" is the same thing we did under the technologist. Are there any comments regarding board and nonboard, et cetera?

[No response.]

DR. PATTERSON: Okay. Then we are down to the 3 months of documented training, and I think the question on

that was should this be a full 3 months, should it be listed into specific hours, would 2 months be sufficient.

Yes.

DR. CARDENOSA: I would say 3 month is a bare minimum, so yes.

DR. PATTERSON: Okay. So we feel that it should be kept at the full 3 months.

Yes, Cass.

MS. KAUFMAN: I think in a residency program on this, it should be at least equivalent to that.

DR. PATTERSON: Yes, Ruth.

MS. McBURNEY: A residency program is not in mammography.

DR. PATTERSON: No. I think what she meant was this period of time in mammography in a residency program.

MS. McBURNEY: Right. Oh, okay.

DR. KOPANS: I don't know if there are data nationally, but certainly, in our residency program, it is 2 months. That is not because we don't think it should be more. It is because of the requirements of residency training, and it is going to get harder and harder, actually, to get more than 2 months as the residency programs contract. They are getting smaller.

DR. PATTERSON: Yes. I think Larry may have the data on that. If I remember correctly, you did that.

DR. BASSETT: We did look at that, and I think it is 2 months is pretty much what the standard is, but you have got to remember here that we are not including in there the physics training and a lot of the other radiological safety issues that are covered in residency programs in different parts and times during the residency, which this alternative pathway we would have to include in there.

So, when you think about all of that and the new conferences and all of the other activities that go on, I think that 3 months is a minimum, but I think it is equivalent to what is going on in residency programs.

DR. KOPANS: I support 3 months. I don't know if it is going to be feasible in a lot of residency programs, but how do you account for lectures in radiation?

DR. BASSETT: That is not what I said. I didn't say I was advocating 3 months.

DR. KOPANS: Oh.

DR. BASSETT: What I said was that 2 months are usually spent directly doing mammography, seeing patients, doing all of the activities that an interpreting physician does. Then, in addition to that, you have got the new conferences, the pathology conferences. You have got your

physics training, and you have got your radiation safety and all of those other things that probably equal out to about 3 months, which is what they are trying to match with this alternative pathway which we are talking about now. We are not talking in this 3 months about the residency program.

DR. PATTERSON: Yes. This is alternative pathway. You are either certified. You see the "or" sort of circled there. You have to be licensed and either certified or have your alternative pathway, which is the 3 months of documented training.

DR. BASSETT: I would agree with Gilda that it is a minimum requirement, and I think it is the closest thing to an equivalency, at least for a minimum.

DR. PATTERSON: Yes, Carl.

DR. D'ORSI: I would agree with what everybody said before.

I think we have to focus on formal, and that will get at the answer to the question of where this training, this alternative pathway, is to take place. What does the term "formal" mean? Does it mean in a residency training program, in somebody's office ad lib, going one night a week to hear a physicist and then going the next morning to look at mammograms? This has to be really defined.

DR. PATTERSON: Okay. Let 's deal with the one question right now on the physicists. Should that be done under a physicist? Any feelings about that?

DR. KOPANS: I would say yes.

MS. KAUFMAN: We are talking about the physics portion.

DR. PATTERSON: The physics portion of this documented formal training for the interpreting physician.

DR. BASSETT: We would say yes.

DR. PATTERSON: Yes. Well, I sort of gather we got the three of them together.

DR. GRAY: The question I would have on that, are you saying any medical physicist, or are you saying a medical physicist is qualified to do mammography?

DR. PATTERSON: That is up for discussion.

DR. GRAY: I would say the latter.

DR. D'ORSI: Absolutely.

DR. PATTERSON: Okay.

DR. FINDER: Let me just ask this, does that medical physicist have to be teaching in a program or can it be any medical physicist?

DR. GRAY: I would say anyone that is qualified to do mammography.

DR. FINDER: Okay.

DR. PATTERSON: Okay.

DR. CARDENOSA: Again, I would continue to have some concerns in that I see as one of the weak links in this Mammography Quality Standards Act the issue that addresses the interpreting physician.

I would move for this being 3 months of mammography plus an additional period in physics. I really would urge the committee to not let the interpreting radiologist get off the hook with having it be all together. I think it is complex enough to learn how to interpret these appropriately. If you are then going to dilute it with hours of physics, I foresee even diminishing what I already view as a small enough amount of time.

DR. PATTERSON: Are there any other feelings regarding that?

DR. BASSETT: Are we talking about the alternative pathway?

DR. PATTERSON: Yes, we are talking about the alternative pathway.

DR. BASSETT: I don't have a problem with that. I think it is not a bad idea.

DR. PATTERSON: Yes, Ed.

DR. HENDRICK: I think, typically, when I think about how much physics residents get specifically in

mammography, it might be 8 to 10 hours a year, and they might rotate through that three times, but they are not getting a huge amount of physics specific to mammography in the residency program. So most of that 3 months is going to have to be clinical time.

DR. KOPANS: This is the alternative pathway.

DR. HENDRICK: Yes, but presumably, we are discussing it in the context of --

DR. KOPANS: I think in a residency program, you are constantly getting physics and whatnot. My understanding, because I misunderstood initially, was this is someone who is not in a residency program who wants to become qualified. I think I would agree with Gilda. They should be trained, learn the physics from a qualified physicist, and then spend at least 3 months in actual interpretation, but I agree to not dilute it, "Oh, come on, we have got to go have our physics lecture for 2 hours," and not actually be looking at mammograms and learning interpretation. So I would say in addition.

DR. PATTERSON: So you are saying that the wording under (2) should read in addition there should be training to include instruction and then go into the medical physicist. Is that what everybody is saying?

Yes, Carl.

DR. D'ORSI: Part of that, if you excuse me, to skip down to where it says you have to interpret at least 240 mammograms --

DR. PATTERSON: I haven't got to that point.

DR. D'ORSI: I know, but it relates to the 3 months. They are going to have to read 240 mammograms in 3 months. By making it an addition, all you are saying is that you hope that by giving them more time that they will read more than 240, which we know that is not going to happen usually in an alternative pathway.

So the fear of not having them interpret enough mammograms is sort of covered by the 240. They are going to have to read this 240 in 3 months. I don't want this to come across like I am trying to get less in for this pathway. If it was up to me, it wouldn't even exist, but it seems that that fear is covered by section (D).

DR. PATTERSON: In other words, you are saying it is going to take 3 months to get the 240 interpretations?

DR. D'ORSI: Well, they have to interpret 240 in this amount of time down here.

DR. PATTERSON: That is a 6-month period of time.

DR. D'ORSI: Oh, that is a 6-month.

DR. PATTERSON: Yes.

DR. D'ORSI: Excuse me. I take it all back.

DR. PATTERSON: Yes, Dan.

DR. KOPANS: I am just wondering if I am misinterpreting this again or not, but the section that you are talking about is really training to interpret mammography, and I would move the physics down to the 60 hours, maybe. Is that the way to do it?

In other words, the 3 months of on-site clinical interpretation of images and then a minimum of 60 hours of medical education in mammography including physics, radiation effects, and so on. Wouldn't that do it?

DR. PATTERSON: Cass, yes.

MS. KAUFMAN: The 60 hours is required for board-certified people, also.

DR. PATTERSON: Yes.

DR. KOPANS: In other words, not to dilute the 3 months for the alternative path, but to have the physics as part of the 60 hours.

DR. PATTERSON : If you do it that way, then you are saying an individual who is board-certified will also have to have additional physics.

DR. KOPANS: Oh, I see.

DR. PATTERSON: It is (A) and (B), and under (B), you have two choices, and then (C).

DR. KOPANS: Sorry. I withdraw the suggestion.

DR. PATTERSON: Okay.

Yes, Mike.

DR. LINVER: Maybe it would be a good idea, then, to really explicitly give a number of hours of training in physics that would be a reasonable number for people who are going the alternate pathway and take it completely out of the training aspect and leave that strictly for interpretation skills. It seems to me that would hopefully resolve this question.

DR. PATTERSON: Okay. That was one of the suggestions that was made about having a specific number of hours, just like the nuclear medicine requires -- am I mistaken? They said 200 hours in physics?

DR. LINVER: That sounds about right, yes.

DR. PATTERSON: And that was one of their comments.

Do you feel that it should be separate, th en, from the 3 months of training and interpretation, and then have a specific number of hours in physics? Do you have a number?

DR. HENDRICK: That is 5 weeks. I don't know anyone who could survive 5 weeks of physics of mammography.

MS. McBURNEY: I think the 200 hours for nuclear medicine includes physics, but it is not totally physics.

So I think it is something like -- I can't remember if it is about 80. I am just guessing.

DR. KOPANS: How many hours do you lecture on mammographic physics?

DR. PATTERSON: Yes, Ruth.

MS. McBURNEY: I think for this 3 months of formal training, the physics wouldn't have to be totally related just to mammography. I think it could be imaging physics. It is talking about radiation physics, including radiation physics specific to mammography, radiation effects and radiation protection.

DR. PATTERSON: You are also talking about radiation safety. You have to remember that these individuals are not radiologists. So they need some basics.

DR. FINDER: I just want t o correct one thing.

DR. PATTERSON: Yes.

DR. FINDER: These people could be radiologists.

DR. PATTERSON: They could be, but they don't have to be.

DR. FINDER: But basically, all it is, they haven't taken boards. A radiologist who hasn't passed his boards would fit in under this category versus somebody else.

DR. PATTERSON: Truth.

DR. FINDER: So it could be both of those.

DR. PATTERSON: One of the comments, which I will get to a little bit later, we had a very extensive letter from the American Society of Family Practitioners who stated that 7 percent of their members have mammography in their offices and that they do their interpretation. So that, you are talking about this number of individuals that would need radiology.

I was shocked at that number, and to quote the latter, at least part of it, they were complaining about the number of mammograms, and this was performing them, but this sort of fits with all of them. It says the time spent performing unnecessary work to meet an arbitrary volume requirement is time a family physician could use for serving patients.

Yes, Ed.

DR. HENDRICK: We were talking about this physics hour issue seriously over here. The typical rotation is about 40 hours through the year for a radiology resident preparing seriously for the boards. There should be some of that, that is devoted specifically to mammography, though. A lot of that is general imaging, physics, and radiation protection, radiation biology.

DR. KOPANS: I could think of at least 6 hours of lectures on different topics, all that have to do with mammography. So I think it is at least 6 hours of physics devoted to mammography, and I would be happy to give those.

DR. PATTERSON: Yes, Barbara.

DR. MONSEES: Just a general question. When this was initially discussed, was there any thought given to separating out the qualifications for interpreting physicians as opposed to the lead physician who was going to be responsible for the QC program, et cetera? Was there any discussion? Do we care to do that or consider that it should be more rigorous?

DR. PATTERSON: No. I don't think we got into that as far as the interpreting physician. I think we talked about that under QC and QA, et cetera, but not under the interpreting physician. Somebody can correct me if I am wrong.

DR. HENDRICK: We didn't actually have the concept of the lead interpreting physician until these proposed final rules came out is my understanding. That is where the concept was first introduced. So it is new to us, too.

DR. HOUN: I think that we had extensive discussion about personnel assignments and should we specify who does quality control tests and who takes responsibility

of the quality assurance program. So we did have discussions on these personnel categories.

DR. PATTERSON: Okay. Any other comments on this? So we are coming up with some number somewhere between 6 hours of physics and 40.

DR. HENDRICK: I think the comment was that for these broad categories of instruction in radiation physics, radiation effects, radiation protection, radiation biology, that the sum should be on the order of 40; that those specific to physics of mammography should be on the order of 6 to 10. Probably, 8 is a reasonable number.

DR. PATTERSON: Okay. Does that seem agreeable to the committee?

How do the Charlies feel on that? Could that be in parentheses, so much in physics?

MR. SHOWALTER: I think we hear the committee.

DR. PATTERSON: Okay. The other major question was who was qualified to teach this 3 months of documented formal training, did it have to be somebody who was qualified to teach in a residency program or somebody who met the qualifications of an interpreting physician, did a residency director meet this qualification even though they did not meet the qualifications of an interpreting physician. I would like some feedback on that.

Yes, Dan.

DR. KOPANS: I don't have an absolute set of criteria, but I think that it at least has to be a practicing interpreting physician to teach interpretation. I think it should be more than that, but I am not sure how you set up the qualifications for that.

DR. PATTERSON: Yes, Gilda.

DR. CARDENOSA: I would suggest that, again, we consider this being done under the guise of a radiology residency. I would hate to think that the family practitioners that wrote in are teaching other interpreting radiologists.

Again, the weak link at this point in mammography is the interpretation, and I think we need to emphasize the interpretation of the mammograms. That is where we are going to find additional cancers at this point, improving interpretation.

DR. PATTERSON: Any other comments on that?

[No response.]

DR. PATTERSON: Okay. I sort of get the sense that it should be somebody who is basically qualified to teach interpretation in a residency program or something along the AA.

Yes.

DR. LINVER: It seems to me that the standards should be no less than for the teaching that goes on in any radiology residency. It has to be at least the equivalent.

DR. PATTERSON: Yes. I thi nk that is a good question. Go ahead and ask, Flo.

DR. HOUN: I know a lot of folks say they get this alternative requirement going to Dr. Tabar, and this would eliminate Dr. Tabar.

DR. FINDER: I just want to bring up that in April, we eliminated Dr. Linver.

[Laughter.]

DR. CARDENOSA: I would challenge that a little bit. What do they do? They keep going to his level one until they get 3 months worth of credits? I mean, I think they may get the continuing CME credits, but I don't see how they could fulfill the 3 months.

DR. KOPANS: I would agree with Dr. Cardenosa on that. For CME credits, that is fine, but you need to be in a program that is seeing real patients and dealing with real questions, not canned cases that are in some kind of teaching file.

DR. PATTERSON: Yes, Joel.

DR. GRAY: I have a curiosity question. What qualifies someone to teach in a residency program as opposed to an interpreting physician in a private office someplace?

DR. PATTERSON: Dan, would you like to respond to that one?

Oh, Larry will respond.

DR. BASSETT: Experience. Basically, experience in teaching imaging of the breast to people who don't know anything about it when they come to you and they are beginning, and they have to leave and pass an examination that is a tough examination, an oral examination based upon what they have learned in your program.

I mean, I can't think of any other standards you can use. What else can you use? I mean, I am not saying it is going to be 100-percent perfect, but it is the best I can think of. Otherwise, it is going to become very arbitrary and individual in terms of if we have to find some way of documenting on an individual basis. That will be impossible.

DR. PATTERSON: I guess my feeling is that I can guarantee you that if your residents were not passing the board in mammography, you wouldn't be teaching very long there. Seriously, I think they would be looking at other ones in residency programs.

DR. KOPANS: Maybe these have to be accredited residency programs, Joel. Maybe that is where you are heading for. I don't know. Can you just call yourself a residency program and have people come and do postgraduate work? I honestly don't know the answer to that, but there are requirements for being a teacher in a residency program in the accredited program.

DR. PATTERSON: Are you talking about the AMNC?

DR. GRAY: That is exactly where I am coming from, Dan, because if we put an requirement like this in, I am sure there is going to be some individuals who are going to have a residency program that is not affiliated with an academic or a certified program.

DR. PATTERSON: Yes, Ruth.

MS. McBURNEY: The way that we have addressed this for nuclear medicine physicians in our State, and we have probably gone over what most of the States have, is that that training, the hours of training, if they are not board-certified, must be obtained in an ACGME-approved institution; that is, accredited for teaching medical education.

If that program that is accredited okays or as a part of that program will okay another course outside of that institution, they are taking the responsibility on for

that training, but outside the regulatory agency of looking at is this person qualified to train or not, puts down on the accreditation process, the accreditation of the medical education.

DR. PATTERSON: Okay. Let me be the devil's advocate on that before Charlie does that.

When you say an ACGME-approved residency, are you saying residency in mammography, residency in radiology or just residency? Because now some of these will say, "Well, gee, I did my OB-GYN and they gave me X part in mammography," or as this family practice thing came up, they says, "Well, they are trained in mammography," and it has listed the aspects.

MS. McBURNEY: It would have to meet those other requirements, but those hours would have to have been obtained in an approved institution.

DR. PATTERSON: That is true.

MS. McBURNEY: That was just a suggestion if that is what people are searching for, for qualifications.

MR. SHOWALTER: I am just mildly concerned that the level of change that we are talking about here could lead us to a re-proposal, and that is fine if that is what we need to do, but I want to caution the committee that, if they want us to proceed post haste with what we have are

small changes based on what we have, we need to be careful about how far afield we range with additional proposals.

DR. PATTERSON: Yes, Cass.

MS. KAUFMAN: Well, it says documented formal training. Could it not be FDA's policy that that means in an approved mammography residency training program? In other words, I am not sure it requires a regulatory change.

My only position is I want to make sure that these individuals have at least the quality of training that the radiology residents have, number one, and number two, I don't want to see just an approved interpreting physician be able to provide this kind of training to another interpreting physician.

DR. PATTERSON: What about the definition of "formal"?

DR. FINDER: Let me just say this. At the last meeting, this issue had come up. I did bring this up with our general counsel, and they felt that a change this major would require a re-proposal.

DR. PATTERSON: Yes, Larry.

DR. BASSETT: I guess what I am concerned about is that what is going to happen is that people within a practice are going to teach each other. I know because I deal with some of these people in one of our programs. They

recently put somebody who just finished a neural radiology residency in doing mammograms because they didn't have enough neural radiology to do. So they just had the other person supervise them while they were doing this until they got enough cases. So this is how they get their supervised cases built up.

Then, what they are going to do is they have someone who isn't board-certified. They will just teach them themselves, the person who is an interpreting physician, because this is the best interest of the practice. They don't want to send them out somewhere else to take their training. This is a big loophole here, and it is all going to happen within individual practices because they are going to have somebody who can't do mammography, and the mammography business builds up or they lose someone who is qualified, and they will just take someone else in the contracting practice, which Dan had mentioned before the problem of contracting numbers of interpreting physicians and so on. I think that is where there is a big loophole here.

DR. PATTERSON: Yes, Joel.

DR. GRAY: I know of at least one practice where this loophole has already been used. There were three radiologists who were not able to pass their board

examinations, and they have been passed through on this by the one radiologist there that did pass his boards.

DR. PATTERSON: But they had residency training in radiology?

DR. GRAY: Yes, but they couldn't pass their boards.

DR. PATTERSON: But that would fall under the 3 months formal training.

DR. GRAY: Right.

DR. PATTERSON: Yes, Cass.

MS. KAUFMAN: Charlie, cou ld you just clarify? I understand about adding on, like, the 40 hours for physics because that really is a new requirement, but could you not make an interpretation that documented formal training, means it has to be in an approved residency program? Could that not be a policy?

DR. FINDER: All I can tell you is the advice that we got.

DR. PATTERSON: Yes, Ruth.

MS. McBURNEY: At least formal training should include some documented syllabus and outline of what is being presented, rather than just sitting down with your colleague and showing them how to read a mammo film or something.

DR. PATTERSON: Carl?

DR. D'ORSI: How far can we go with the definition of formal? If we can't go to what we all want to go to, which is basically a residency program, what can we do to obviate the obvious problems that are occurring? I mean, this is a huge defect.

DR. FINDER: Well, we have addressed the formal issue already.

DR. D'ORSI: What is it?

DR. FINDER: It has to be a formalized program --

DR. D'ORSI: What does that mean?

DR. FINDER: -- in order to be able to document just what you were saying, that these areas were covered and that kind of stuff.

DR. D'ORSI: That is it?

DR. FINDER: Well, what else?

DR. KOPANS: Just a letter saying that these topics were covered, that makes it a formal program?

DR. PATTERSON: Does the FDA have the ability to say this meets or does not meet the requirement?

DR. FINDER: Yes.

DR. KOPANS: It seems to me that MQSA -- I mean, one of the concerns that we talked about yesterday was the ability to interpret mammograms, and if you don't have some

kind of requirement for truly formal training, everything goes down the tubes. The buck stops with the interpreting physician.

To not have some more rigorous qualifications than just as Larry was saying, I read my 240 mammograms under the supervision of some interpreting physician and/or I spent 3 months in the department with that physician, I think, is a mistake.

DR. PATTERSON: Okay. Any other comments?

Yes, Esther.

MS. SCIAMMARELLA: I agree as a consumer that we need to be more specific about qualification of the interpreting.

DR. PATTERSON: Okay. I think you heard our concerns. We probably gave them before in April, but I think the public is asking the same questions.

Let's go to the next one.

[Overhead.]

DR. PATTERSON: This is still under the initial requirements, and it is a minimum of 60 hours of documented medical education in mammography with instruction in interpretation, at least 8 hours of category I in each modality, and this was one of the questions asked. Here again, we had all over the board on this.

In addition, we said that 40 hours had to be in category I and at least 15 hours in category I in the 3 years prior to starting to interpret. We had people that agreed. We had those that disagreed.

I think that the agreements and the disagreements were probably pretty much equal there. There were some that felt that 40 hours was enough. There were others that asked, well, you know, 40 was sufficient for the interim, why are you going up to 60 and take it back to 40.

There were those who said that 60 hours in category I was wonderful. There were others who said why don't you allow category II, and they talked about the hardship, et cetera.

One of them said if they are qualified, they don't need any of these hours in CME. They said you don't need any of this to read mammograms, and you certainly didn't need to go to CME courses because these were all done by the same "gurus" who give nothing but the same repetitious thing over and over again, and they didn't get anything out of those hearing the same ones 60 times.

There again was the question who was qualified to give these, was somebody was just in active practice or should they just be in active practice or could they be somebody who only taught, and they wanted to further define

activities in these CME courses to include technique and QA and QC. So some of them wanted each of these things to be designated individually.

There was also the big confusion or comments about what did they mean by each modality, and they was one that said this all should be called breast imaging and not mammography and, therefore, ultrasound and MRI, et cetera, would be a part of it, but if you say mammography, then who is keeping track of just the mammography, et cetera. That was a comment that was given both in this and in the following CME questions.

Comments regarding that? I guess the first is because there were comments that said that 40 hours was enough, do we still feel -- and if I remember correctly, w recommended the 60 hours the last time around or agreed with it, and I don't know if we still want to go with that.

MS. KAUFMAN: I thought the last time, we said it all had to be category I.

DR. PATTERSON: Yes, I believe we did, and we said all of it was category I, and we felt the 60 hours, with the public comments. Does anyone with to change any of that?

[No response.]

DR. PATTERSON: You can ask it now.

MS. KAUFMAN: The FDA asked the question, it has been suggested that all 60 hours be category 1. In view of the fact that this requirement is already included in either the board certification or 3 months of training routes, should the 60-hour requirement be dropped?

DR. PATTERSON: Comment? No change?

DR. FINDER: Can somebody explain that to me?

DR. PATTERSON: You are the one that asked the question.

DR. FINDER: I know the question. I don't understand the answer.

As far as I can tell, unless somebody has another rationale, this doesn't add anything. The 60 hours are either included in the board certification or the 3 months. It is included. It is not an addition. So what are we gaining by that?

DR. PATTERSON: No, no, no, no, no. It doesn't say it in the 3 months that you must have --

DR. FINDER: It says hours spent in residency can count for this.

DR. PATTERSON: Right.

DR. D'ORSI: It doesn't cover the alternative.

DR. FINDER: What is the alternative?

DR. D'ORSI: The alternative pathway also has to go through (C) and (D).

DR. PATTERSON: Right.

DR. D'ORSI: So I would like to make it 150 hours now in relation to what just went on before. Anything that I can do to make it more difficult for somebody to take an alternative pathway, I would like to happen.

DR. FINDER: But it doesn't make it any more difficult.

DR. D'ORSI: It gives them more time to spend doing this. It means more better time spent in doing this.

In other words, the way I read this unless I am not reading it correctly, everybody has to have (A). Everybody has to have (B)(1) or (2). Everybody has to have (C), and everybody has to have (B).

DR. FINDER: Right.

DR. D'ORSI: Right. So, if you are in a residency, you are easily going to cover (C) and (B).

DR. FINDER: Right.

DR. D'ORSI: If you are not, it is going to cost you more of your personal time to cover (C) and (B), which made deflect some people form going through an alternative pathway.

DR. PATTERSON: I think a couple of things that are under (C), number one is that it says at least 15 hours must be in the past 3 years. So that, an individual said, "Well, gee, I got a 3-months, 20 years ago." No?

Yes.

DR. KOPANS: I am a little confused again here, but I think, Carl, what I would suggest is that the 60 hours be in addition to the 3. I think that is didactic for the alternate pathway.

DR. D'ORSI: Well, that is the way it is written.

DR. KOPANS: No, it isn't. I think what Charlie is saying it is within the 3 months.

DR. D'ORSI: Right. It is within the 3 months.

DR. KOPANS: Well, that needs to be clarified.

DR. PATTERSON: If it is in the residency program, if you look at the last --

DR. D'ORSI: That is only for the alternative, Dan.

DR. PATTERSON: The last six or eight lines, under (C), it says hours spent in residency specifically devoted to mammography.

DR. D'ORSI: Which is (B)(1), not (B)(2).

DR. PATTERSON: So that takes care of the (B)(1). It is the (B)(2).

DR. KOPANS: So that is an additional 60 hours over and above the 3 months?

DR. PATTERSON: Right.

DR. KOPA NS: Charlie, is that --

DR. PATTERSON: And this must include basic breast anatomy, pathology physiology, technique, QA, and QC.

DR. D'ORSI: Did you hear that? The 60 hours for the alternative path was over and above the 3 months.

DR. PATTERSON: From what I can gather, the 3 months is in formal training in interpretation, and also, in that, there is instruction in physics.

DR. KOPANS: In addition, a minimum of 60 hours?

DR. PATTERSON: Then, you need 60 hours of medical education, documented medical education that includes all of the other breast anatomy, physiology, QA, QC, et cetera, et cetera.

Yes, Carl.

DR. D'ORSI: You are right, Charlie. In a residency, it is redundant, but not for the alternative pathway, and that is the key now that we have this apparent inability to make the formal training what we want. So I think that is great.

DR. FINDER: Okay. So you want to leave it in?

DR. D'ORSI: Oh, yes.

DR. FINDER: Okay.

DR. PATTERSON: Okay. Yes, Larry.

DR. BASSETT: I just want to c larify a couple of things because I spent a lot of time -- I think it is a couple of years ago now -- with people here, Charles, before you were here, working specifically on these particular things.

What we came to a conclusion about at that time was that if the resident should have had these hours during their residency and that when they passed the board exam, at that point, the date on their board examination certificate would begin the clock ticking for when they had to accumulate the 40 cases per month over time. They didn't have to start with the 240.

So that, in a residency, if you took the required time in mammography, passed your exam, your oral examination, then you basically accomplished all of the requirements to be an interpreting physician to that day, the day that you passed, and then your requirement was to continue to accumulate the requirements that any other interpreting physician would, which is 15 units of CME every 3 years and reading the requisite number of examinations.

DR. PATTER SON: That is the continual experience.

DR. BASSETT: Right.

DR. PATTERSON: We are still on the initial qualifications.

DR. BASSETT: I understand. No, that is what I said. That is how you got your initial qualifications, by finishing your residency and passing the exam, and then you began your continuing requirements, but if you didn't pass your exam or you didn't do a radiology residency, then you had to use this alternative pathway.

So, to me, at least I thought it was spelled out, you had to take an alternative course that would qualify you as having met the requirements you need, but you didn't pass the exam, so you must not have gotten it before, and you had to accumulate the CME requirements before you could begin to interpret mammograms. I suppose you also would have to have 240 read under supervision.

DR. PATTERSON: Yes, Barbara.

DR. BASSETT: Isn't that correct? Isn't that the way everybody remembers it?

DR. MONSEES: If that was the sentiment, then there are two ways that you can get into the alternative pathway, but (C) says that hours spent in residency could be credited. So, even if you didn't pass the boards --

DR. BASSETT: Right.

DR. MONSEES: -- the way this is written now, if you fail your boards, but you trained as a radiology resident, you can use your hours during residency.

DR. BASSETT: That is why I brought this up.

DR. MONSEES: What you are saying is you need supplemental training if you failed your boards. That was the sentiment.

DR. BASSETT: I think we have to a ddress it is what I am saying.

DR. MONSEES: Right.

DR. BASSETT: To me, I saw it that way at the time, but I can see there is a little bit of a loophole here.

Now it occurs to me, while all these people who didn't pass their boards are showing up at my door asking for -- I didn't quite understand what they were asking for, but I think I do now.

[Laughter.]

DR. BASSETT: They want me to verify the hours they spent, like, 10 years ago in residency or something.

DR. KOPANS: But in addition to that, I a m still confused. I think Charlie was suggesting this, and maybe I am just confusing what Charlie was saying. For the alternative pathway, whether it is a radiology resident who

has failed his or her boards or it is another physician that wants to read mammograms, the 60 hours of medical education in mammography is in addition to the 3 months of clinical training which is listed earlier. Is that correct?

DR. PATTERSON: That is correct.

MS. McBURNEY: No. If they were in a residency program, then, as proposed, the hours count.

DR. PATTERSON: Yes.

DR. KOPANS: Let me back up, then.

DR. BASSETT: But if they passed or not?

MS. McBURNEY: Right.

DR. KOPANS: Let's take the situation of not a radiology resident. Let's just take the alternative pathway for a pediatrician. That person would have to do 3 months of what I see as clinical training. In addition, 60 hours of medical education, and the 60 hours is not within that 3 months. Is that correct?

DR. PATTERSON: Correct.

DR. KOPANS: That nee ds to be clearly spelled out because I am not sure, to me, reading this, the 60 hours could be within that 3 months.

DR. PATTERSON: No, it doesn't say that. Only for the radiology resident.

DR. KOPANS: I am just talking about the alternative nonradiology resident.

Now, the issue of the radiology resident who fails his or her boards, that is, I think, a separate topic, but I think it needs to be clear that the 60 hours for these nonradiology resident is over and above the 3 months.

DR. D'ORSI: You ha ve to have (A), (B)(1) or (B)(2), (C), and (D).

DR. KOPANS: But I would say in addition, have a minimum. I can see interpreting that as 60 hours within my 3 months.

DR. PATTERSON: No. The way it is written is that you have to have (A), (B), (C), and (D). (B), you have two choices for it either way, but you still have to have (C) and you still have to have (D).

DR. KOPANS: But it is not clear that (C) has to be in addition to the 3 months for (2).

DR. PATTERSON: Yes, Ed.

DR. HENDRICK: I think it is clear, Dan. It is refreshing, though, to see the radiologists have awaken to the rulemaking process here.

[Laughter.]

DR. PATTERSON: Yes. It is the way they write regs. It is not part of (B). It is separate as (C).

DR. KOPANS: As long as FDA has an interpretation of these different subheadings, that is fine.

DR. PATTERSON: They have an interpreting physician up there.

DR. HENDRICK: Every one of these is like that.

DR. PATTERSON: So we are saying not to do away with the 60-hour requirement. We are saying it should be category I. Did we address any of the other comments?

DR. KOPANS: I would like to propose that the resident who failed falls into the same category as the physician who is starting from scratch.

MS. McBURNEY: That is going beyond.

DR. PATTERSON: What was that? Wait a moment. The resident that failed would be basically under the alternative pathway. So they would have their license under (A). They would be (B)(2) which would be the 3 months of formal training. They would need the 60 hours -- oh, no, they wouldn't because that would be part of their residency.

MS. McBURNEY: Right. That would be going beyond what was proposed.

DR. PATTERSON: Yes.

MS. McBURNEY: I don't know that they could do that.

DR. PATTERSON: As it says there, if it is documented in writing by the appropriate representative from the training institution, I guess that would be the loophole on that, if they didn't sign off on it.

Yes, Joel.

DR. GRAY: I would have assumed that the intention of this was to only apply the last sentence in section (C) to someone under (B)(1), and perhaps it is just the way this was worded. Was that not the intent originally?

DR. PATTERSON: I don't know if it was the intent or not, but it is not the way it is written.

Yes, Carl.

DR. D'ORSI: Why isn't he right? Why isn't the definition of residency thrown back to (B)(1) which means certified and passed? Why isn't that true? It says in there residency, but we don't define residency. What does that mean? Does the residency count if you pass or don't pass?

DR. KOPANS: As it stands now, it does.

DR. FINDER: Let me ask this question. If you finish your residency program and don't get certified, are you a radiologist afterwards?

DR. D'ORSI: Well, that is open to debate.

[Laughter.]

DR. FINDER: Well, that is the point.

DR. D'ORSI: Yes. Well, okay. I tried.

DR. PATTERSON: Okay. Barbara?

DR. MONSEES: I'm sorry. Maybe I misunderstood Dr. BASsett's comment, but I thought he was saying that the sentiment was that you had to.

DR. PATTERSON: It may be the sentiment, but it is not the way it is written.

DR. BASSETT: I am just trying to review this because I see some potential things. I am not sure which is the most appropriate, to be honest with you. I mean, it seems like what Elizabeth said is correct, that they did meet the CME requirements as written, and it becomes very arbitrary, then, when you say that theirs doesn't count and the other person who did the same things did. It is for everybody, including the woman having the exam. I mean, I don't know what the most fair thing is.

DR. KOPANS: Just to throw another curve into the problem, let's say they failed their boards, in jest, in GI.

DR. PATTERSON: Yes. I think we sort of have to go with the way it is written here.

Yes, Ed.

DR. HENDRICK: I think there is still a difference. Somebody who has gone through 4 years of

residency training has a lot more exposure to image interpretation to the basics of imaging to the physics of imaging than someone who gets this alternative 3 months of formal training and hasn't gone through a radiology residency.

I mean, a residency is 4 years, right?

DR. PATTERSON: Yes.

DR. HENDRICK: So I think it is worth a little bit of a break.

There is also the question under (2). If they don't pass their boards, then they fall under (B)(2), and they might not actually have had 3 months of documented formal training in interpretation of mammograms within the residency. If they are not board-certified, they may have to go back and get some additional training in order to meet (2). So I don't think it is all bad the way it is written.

DR. PATTERSON: Can we move on, on this, then? The comment about interpret the 240 under direct supervision of a qualified interpreting physician within the 6-month period, again, there was the question about who was qualified to teach these interpretations.

Then, there was the question about the residencies, and we had quite a number of residency program people who wrote stating that they weren't all going to be

able to get all their residents in the previous 6 months prior to this, eliminating the exception which -- I don't know. Maybe they didn't come to that or they wrote their letter beforehand or what have you, which allows the resident, and we will get into that under the exceptions, but is there any comment about the interpretation of the 240?

As I said, most of the questions were just on who was qualified to do this.

Yes, Carl.

DR. D'ORSI: I'm sorry. I lapsed ou t for a minute.

DR. PATTERSON: All right.

DR. D'ORSI: Does that 240 still mean that they have to do it in their last 6 months of training as a resident?

DR. PATTERSON: No.

DR. D'ORSI: Okay. I didn't see that. All right.

DR. PATTERSON: Okay. Yes, Cass.

MS. KAUFMAN: In looking through the comments, I am not positive, because I read the whole book, but it seemed to me that there was some question about grandfathering because there are interpreting physicians who -- oh, that has those comments?

DR. PATTERSON: Go on.

MS. KAUFMAN: Because there are interpreting physicians who we have approved under the interim regulations who won't meet these requirements. So I am just asking, are we going to not allow them to continue acting as interpreting physicians?

We said they only had to have 180 hours of evidence of --

DR. PATTERSON: Here again, that falls under the exceptions, which we will get to in a moment.

If you look down in the middle of the column, the second column where it says those physicians who previously qualify as interpreting physicians under the FDA interim regulations are considered to have met the initial requirements.

MS. KAUFMAN: Okay.

DR. PATTERSON: Okay. So we will get to that under the exceptions, but this is for individuals that are new coming on board.

Any additional questions on that?

[No response.]

DR. PATTERSON: Okay. I think I address all of them because most of the comments on that was basically looking at residents type of thing.

[Overhead.]

DR. PATTERSON : Let's go to the continual experience and education. Under (A), you must have an average of 40 over the 24-month period, and again, we have all over the board, some agreed, some disagreed. Some said no, this should be closer to 200 per month. Some said no, this is too much, we don't do that large a volume, and therefore, 40 is too much. Some of them said you should be averaging this over a 1-year period of time and not a 2-year period of time. Some of them got into the question of the double reading for this number, and somebody said if you have more than one person reading it, then it becomes multiple reading instead of double reading.

I read you the comment about this was unnecessary work to keep up volumes, this arbitrary volume requirement, and it took time away from patients.

There were those who wanted clarification, did you allow this independent or could this double reading be together type of thing. Some them said it had to be double reading without any marks put on the films to identify the area that you are concerned about.

Some of them wanted to know if you didn't keep up that number, could you just use CME in lieu of interpreting mammograms because you really didn't need a lot of skill in

interpreting mammograms. I mean, some of them were pretty interesting. I mean, it is easy, so all I have to do is keep up my CME.

Some of them said if you are a well-trained radiologist, why would you need to do 40 a month if you have been doing them for a long period of time. There were those that said you should have a maximum, and then there were those that said you shouldn't have a maximum number that you can do.

Then, there was the question of, well, you should relax your requirements for rural areas. So those were basically the whole group of comments of the continual medical experience.

Any comments? Keep it as it is.

I think we have said over and over again, people in the rural area shouldn't get lesser quality. So is there anyone who wants to relax it for rural? No.

Is there anyone t hat thinks there should be a maximum or not be a maximum number read?

DR. KOPANS: Why would you have a maximum? Twenty seconds to read a mammogram might not be a good situation.

DR. PATTERSON: Okay. The question, then, about if you are well trained and you have been doing it for a long period of time, do you really need the 40.

Do you need to do them independent or can you do them together for your double reading, or don't you really care as long as you are reading them?

[No response.]

DR. PATTERSO N: No comments.

DR. HENDRICK: Don't you have to sign the interpretative report? I mean, isn't that what you mean by reading is that you have signed a report?

DR. PATTERSON: Well, there are some places that they use to interpreting physicians on the report, and the question is, have they been read independently at two separate readings or are they reading them together, basically, or are they comparing their results before coming out with a final report on it. I think that is basically what they are saying on it.

DR. HENDRICK: I guess I thought whoever was the official signature on the report is the one who is credited with the reading.

DR. PATTERSON: There are a number of places that are actually doing double readings, and two names are going on every report.

DR. HENDRICK: They are not two independent reports?

DR. PATTERSON: No, no. Two names on one report.

DR. HENDRICK: Well, I leave it to you radiologists to figure that one out.

DR. PATTERSON: Yes, Ruth.

MS. McBURNEY: And I thought we were allowing the double reading in the small-volume facilities in order to meet this requirement.

DR. PATTERSON: Yes. We were allowing it. I think they wanted clarification, did they have to be independent reports or could the reports be together to meet those numbers, I think, is what they were questioning.

Yes, Rita.

MS. HEINLEIN: I think the question is, were they read independently or do they both sit there together and read it.

At some facilities, only one name goes on the report, and they just have a method of documenting that a second physician did a second reading. So I don't know if it is a matter of issuing any type of a report or that is how they would document it. I think it is a matter of did they sit there together and read it or were they independent in reading it, aside from the documentation.

DR. PATTERSON: I guess the question is, does it make a difference.

Yes, Dan.

DR. KOPANS: I think we have a double-reading system where we actually don't put two names on the report. The reason for that is to benefit the patient and not benefit malpractice lawyers, but we do document and keep track of who the second reader is for this purpose. So I think you should have some documentation that the second reader really did look at the mammograms, one way or another.

DR. PATTERSON: But independently? I think that is what their question was.

DR. KOPANS: Oh, you mean if you sit next to each other?

DR. PATTERSON: Yes.

Yes, Carole.

DR. CHRVALA: I think it has to be done independently. If they are sitting next to each other, they are going to influence each others judgment. They have to be done separately, and they usually assign a primary reader and then set aside a set of films that are going to be double read, and they are distributed among the other radiologists. They are read at a different point in time, not when the first interpreting radiologist takes a look at the exam. I think the opportunity for bias is pretty high.

DR. PATTERSON: Larry?

DR. BASSETT: I don't think thi s is about the issue of double reading in order to improve sensitivity. What it is really about is having enough numbers --

DR. PATTERSON: Right.

DR. BASSETT: -- to meet the qualifications, and I think what the intent was, if someone else had officially read the images, you could review them all and put your impressions down. This could even happen if you weren't even at the same facility.

If a facility had a low volume, they could have an arrangement with another facility to go over all the cases and make an interpretation. I think this would happen in the military specifically or more commonly.

So the purpose here is not for a double reading like you talk about in the research papers, but to accumulate enough cases for the people who are in low-volume facilities, so they can document that they actually interpreted or read enough cases to meet the qualification. Right?

DR. PATTERSON: Yes.

DR. CARDENOSA: I guess I would remain a bit concerned about how that is going to be documented because I suspect that if your name isn't going on the report, you could get through 240 mammograms in an hour. So I guess I

would want to see what is the documentation to be sure that people have truly reviewed the mammograms appropriately. How is that documented? I don't see anything specified as to how that is going to be accomplished.

DR. PATTERSON: Barbara, I saw your hand.

DR. MONSEES: I just wanted to say that I agree with Larry. The idea is that this is about training your eyes. In fact, if it were 240 cases that were teaching cases where you read them as unknowns and you got path feedback immediately by looking at the answer, it would be even better, but it wouldn't be an on-line reading. You would learn as much or more, and you would train your eyes. So I don't think it should be about, necessarily, on-line. Let's be realistic here. It should be about getting the experience and getting some sort of feedback.

In terms of documentation, maybe an attestation form is really all we need here, or maybe we need to have somebody track how many they read in a particular way and keep that for their own documentation.

DR. PATTERSON: Yes, Rita.

MS. HEINLEIN: Doesn't the ACR right now under -- well, even under the voluntary program, wasn't there some requirement that the physician interpret so many mammograms under that? Am I off the wall here? Wasn't there something

like that? Was there some method? What methods were accepted for documentation on that if they wanted to do double reading, like, say in a lower-volume facility?

DR. PATTERSON: Yes.

DR. HOUN: I guess I would suggest that we not specify the systems for how double reading, if you are going to do it, happened because I don't think we need to be that prescriptive.

DR. PATTERSON: I agree. I think how you maintain it and keep your records is probably -- I am just bringing up the comments that the public asked.

Yes, Cass.

MS. KAUFMAN: We have had several fc

DR. HOUN: We have had several facilities who are under that breast cancer detection program where they get money, I think, from CDC, and their physicians say they are interpreting, like, 1,500 mammo films a months.

Then, we get a little concerned about how much time they are spending on each film, can you interpret that many and still do an adequate job. So do we need to think about having some kind of a maximum or something in there on that?

DR. PATTERSON: Yes, Dan.

DR. KOPANS: I think Gilda's point earlier is a good one. We really don't know the shortest period of time it takes to read a mammogram. So I think it would be tough to set a limit. That is all I would say. I don't know what is the maximum. Also, how quickly do you get tired out? I mean, I get tired after looking at 40 screening mammograms. I have to go do something else, but I am not sure you can legislate that again. I don't know what the answer is.

DR. PATTERSON: Yes, Mike.

DR. LINVER: Just to corroborate that, I think there is too much difference in the kinds of interpretations that are going on. If it is all screening and if it is in a population, especially, of older individuals, the time involved is going to be a lot less than if it is younger patients with more difficult patterns. So there is too much variation, I think, to try to legislate that.

DR. PATTERSON: Marsha?

MS. OAKLEY: I appreciate what Cass is saying about screening programs, but in the State of Maryland where managed health care is making tremendous changes, there are many private practices that are now in the huge systems and huge volumes of mammograms that are passing across desks. So I have concerns not just for the patients who are in the CDC programs.

DR. PATTERSON: Yes, Joel.

DR. GRAY: I have a question regarding a fairness issue here, and this goes back to what we were talking about with the technologists earlier. What did we decide that we would allow if one technologist is in a room with another? Do they only get credit for half of an exam, or did we decide both get full exam credits?

DR. PATTERSON: Yes, but that is performance of and that is not interpretation of. I mean, a mammogram can go -- and we established this a long time ago, that the same mammogram could go from a dozen different places. It is the experience of interpreting the mammogram.

DR. GRAY: I agree with that same mammogram to go to a dozen different places, but we are talking about now the difference between two people interpreting it simultaneously or independently, and I just think we ought to keep that in mind.

DR. PATTERSON: Oh, I see what you are saying. So you are saying that this should be independent interpretation.

Yes, Carl. Can we move on?

DR. D'ORSI: (D) says direct supervision. If you turn to the definitions, direct supervision means that during joint interpretation --

DR. PATTERSON: Excuse me. Let me cut you off real quick. We are past (D).

DR. D'ORSI: Oh, I'm sorry.

DR. PATTERSON: We are now on (2)(i).

DR. D'ORSI: I was just thinking backwards.

DR. PATTERSON: Okay, but that is initial training. We are now in continual experience. Please, let's not backtrack. We will be here until tomorrow morning.

So we are basically saying the feeling is it should be independent.

The other question was, did we feel it should be closer to 100 a month. I think there was only a few of them that said that this should be per year and not over a 2-year period of time.

If you remember correctly, we used the 2-year average over the 2-year period of time for people that were on sabbaticals and this type of thing.

Yes, Rita.

MS. HEINLEIN: Can I ask a question?

DR. PATTERSON: Yes, you may.

MS. HEINLEIN: I say this hesitantly. What did we decide about could they read together or apart?

DR. PATTERSON: I think we said that our feeling was that it should be independent, but I think Flo sort of asked us not to get into legislating how things are done. I think our feelings were made. Maybe somehow or another, this will get into the preamble that we feel this should be independent. I think that was the consensus of everybody.

Part (B) -- we are moving right along -- is under the CME, which states that it should be 15 hours in category I over a 3-year period of time, and that at least 6 hours in category 1 in each modality.

Here again, we got the question, what did you mean by modality. The other question was that this should really not be mammography, but breast imaging because these places are doing ultrasound and MRI, et cetera, which don't fall under this, and can they use their credits in that aspect.

We had pros and cons o ver the numbers. Some said that 15 was too low. Some said it was too high. Some said it shouldn't be over a 3-year period of time. Some said it should be on a lesser period of time. We had them all over the board there.

There were some of them that felt that there should be no requirements whatsoever for CME, and the quotation was that they would choose what they think they need for what they think they need.

There were others that felt that because of the change in technology, this number was too low and that it should be increased because technology is changing. They felt that the time period should be shorter because of the changing technology.

Then, there was a couple who said, really, the only type of CME that should be allowed would be either hands-on or viewbox type of a CME and not going to a course. So that was the gamut of the comments.

Any comments about those?

[No response.]

DR. PATTERSON: I guess the biggest question is, should it be all-encompassing under breast imaging rather than just mammography. I think that was one of the things that needed -- maybe somewhere along the line, maybe in the preamble, that needs to be defined, whatever the committee feels about that.

Yes, Rita.

MS. HEINLEIN: In this law, it has been specifically defined as to what mammography is. I mean, I think if now we go to change it to breast imaging, all we are really be doing for the sake of this law is to take out the word "mammography" and still define breast imaging as

"as mammography is currently defined in this regulation." Is that correct?

DR. PATTERSON: No. I think the question was when they go to a course in CME, if they are getting, say, 15 hours and some of this is involving ultrasound or MRI of the breast, could this be counted or did it all have to be on "mammography."

MS. HEINLEIN: Oh, I see what you are saying.

DR. PATTERSON: Yes, Dan.

DR. KOPANS: I think for all these other modalities, they are always somehow integrated with the mammographic evaluation. I don't think I have ever been to a course where someone just talked about breast ultrasound and didn't show a mammogram. So I don't see it as a problem.

If you go to some course where there is no mammogram shown, there is no integration, then I don't think you should count that, but I can't envision a course like that.

DR. PATTERSON: No. I think they were talking about the reverse. If they went to a course that said you have 15 hours of CME and in that there was, say, 3 or 4 hours that was on ultrasound of the breast, this is a breast

course, and there were 3 or 4 hours on ultrasound of the breast, could this be included in their CME.

DR. KOPANS: That is what I am saying, that ultrasound of the breast is always integrated. They are inseparable. So I would say yes, it would be part of that.

DR. PATTERSON: Yes, Flor.

DR. HOUN: I think what we circulated to the committee, I guess, in December about the proposal for how to count continuing education on the interim regs is that no more than 50 percent of the continuing education credits can be in related topics.

We recognize that related topics such as ultrasound of the breast, MRI of the breast complement performance interpretation understanding of mammography, but if you just did 15 hours totally of MRI of the breast in a 3-year period, that was all the education you got, you couldn't really say that that helped you along totally in mammography.

So that was the proposal we had circulated to the committee members in December for how we would do it under the interim regs. How it differs is that this proposal is stricter. You can only get all 15 in mammography.

DR. PATTERSON: Yes, Penny.

MS. BUTLER: I would think -- and I would like to hear more from the radiologists -- that courses on ancillary imaging modalities used for the breast is really part of the total breast care picture. How can you really separate it out? I think it should be included for continuing education, even though it is not specifically mammography.

DR. PATTERSON: I guess the problem is on he re, it says in mammography, and then, in the beginning, under definitions, it talks about mammography as radiology of the breast. That is what people were asking, what did you mean.

Yes, Barbara.

DR. MONSEES: There are many things that we might learn as radiologists that would pertain to the practice of radiology and interpretation of mammograms, radiologic/pathologic correlation, epidemiology, for example, anatomy, things like that, that will influence the way we practice, the way we screen, for example, the number of call-backs, et cetera, things we learn from studying outcome data, other people's outcome data, that don't really pertain to looking at images or how to look at images, et cetera, and I think they should be counted.

Likewise, as Dan was saying before, when you take a course and somebody teachers you the MR correlate for the mammogram in the clinical picture, that is teaching you kind

of advanced training. That is very important, and that should be considered CME, I believe.

DR. HOUN: I would ask, would you consider just extending what we have proposed under the interim regs to this? In other words, no more than half of the continuing education credits be in these related topics because the situation is if you only get 15 in 3 years, if it is all in breast cancer epidemiology, is that going to assist your interpretation.

DR. PATTERSON: Yes, Barbara.

DR. MONSEES: I think if you are to that point in your career where that is all you really are needing to learn because you are so proficient at the rest, I think that it does count. I frankly think that it could be counted.

DR. PATTERSON: Then, you are the type of person that says don't tell us what we need. That was one of the quotations.

DR. MONSEES: Thank you.

DR. PATTERSON: Dan, you had a comment.

DR. KOPANS: Let that side go for a second.

DR. PATTERSON: Okay. We will start at the end. Bob?

DR. SMITH: I like the idea of 15 hours of epidemiology.

[Laughter.]

DR. SMITH: I don't think they should end with that. They should start with that.

DR. KOPANS: It's a good nap.

DR. SMITH: I am just opening with something facetious.

One of the things I have a question against, I am sort of worried about inspecting against this by scrutinizing the title of courses. I sort of like the idea of the general guidance about the relative proportions, and I think that the comments made by the radiologist about the broad spectrum of issues covered in the actual CME course is very important and it is telling.

I am worried about somebody looking at a course that says breast imaging and saying that just really is not mammography. I think this may be an inspection issue that we have to be mindful of as we start scrutinizing course titles and their content.

DR. PATTERSON: Penny?

MS. BUTLER: I think using the model of 50 percent, not more than 50 percent can be other imaging modalities, is an unnecessary complexity which really can

complicate the inspection issue. We should just specify 15 hours and leave it at that and let the individual choose what they need to round out their continuing education.

DR. PATTERSON: Ed?

DR. HENDRICK: I was just going to appeal for sort of a reasonable approach to this. Nobody is going to design a course that is 15 hours of epidemiology for radiologists.

DR. PATTERSON: Bob Smith.

[Laughter.]

DR. HENDRICK: Okay. They might design it, but nobody is going to go to it.

If we had a problem out there of people giving sham courses for CME and only giving them epidemiology when they really needed interpretation, we might need to micromanage this, but that is not the situation.

These courses are designed to be reasonable and to really aid radiologists, and that is what they do.

DR. PATTERSON: Do the Charlies have any comments to make?

Yes, Rita.

MS. HEINLEIN: I think Ed brings up a good point, and I think that that should be the same for all the continuing education requirements for each of the personnel. I mean, the physician, the technologist, and the medical

physicist. Instead of specifying so much at a certain percentage, just let them make the decision as to what it is they need because they have already received the initial training. This is in an effort to help them continue so they can know, if they do have a weakness, where they need to improve.

DR. PATTERSON: Yes, Cass.

MS. KAUFMAN: Well, I was just going to say that the proposal that Charlie Finder faxed to us that kind of divided continuing education into four categories worked for technologists and M.D.'s and physicists. I guess I just want to make sure that we don't have somebody attend a course on, for example, how to increase your profit margin in mammography or something like that, counting towards continuing education in mammography.

I thought that the four categories that was proposed by FDA worked pretty well, and we have some experience with that under the interim regs.

DR. PATTERSON: Yes, Barbara.

DR. MONSEES: That is not medical. I don't consider that medical. Profit margins are not medical.

DR. PATTERSON: So you a re talking that they should be medical.

Yes, Ed.

DR. HENDRICK: Thank you so much.

DR. PATTERSON: I am just getting tired.

DR. HENDRICK: These things have to go through CME approval for category I credit. They have to have feedback from participants. They have to have critics of the courses. They have to meet certain criteria. Let's leave it to the professionals to do that, not the FDA.

DR. PATTERSON: Okay. I will just be the devil's advocate on this. You can still have profit things and managed care and still get CME.

DR. KOPANS: There is no way to make a profit out of screening mammography.

DR. PATTERSON: That is for sure.

DR. KOPANS: I think if you try and micromanage this, would a course on complying with MQSA be legitimate? I think it would be.

DR. PATTERSON: Okay. The other comment, just to bring it up, was regarding the hands-on or the viewbox type of thing. My feeling is they are good, but I don't think they should be required.

Next slide.

[Overhead.]

DR. PATTERSON: The q uestion regarding the new modality was it is written that it is 8 hours before you

start independently with a new modality, and here again, we had all over the board, you don't need it, it is too high, 5 hours is enough. There were some who felt we were talking about Xerox and said you shouldn't have any of that. Some of them said new modality was too vague. We heard that earlier.

They wanted the training to be clarified, like when and how, and somebody made the comment, "Well, not only should you get training in this new modality, but you should have training in interpreting a certain number with somebody who met the qualifications of this new modality under supervision." In other words, if you are going to be reading digital images, you need to be trained under somebody, a certain number of them.

I think that was about the only comments about the new modality, too high, too low, et cetera. Any comments about that?

Dan.

DR. KOPANS: I'm sorry. What is the requirement, actually? Let's take digital.

DR. PATTERSON: Okay. It is 8 hours before you start interpreting using a new modality.

DR. KOPANS: The interpreting of digital images, I would agree with whoever wrote that saying it is still a

mammogram. It is just figuring out the knobs and what contrast level and window levels you want. I don't know how to deal with that because I don't think anybody knows, A, how we are going to be interpreting these and, B, how long it is going to take to figure out the knobs, but I don't think the actual interpretation of the image is any different from a mammogram. So I don't know how to set a time on that.

DR. PATTERSON: So do you think that at least 8 hours of training in the broad category of the new modality is acceptable? In other words, can I come to your place and spend 8 hours?

DR. KOPANS: Would you count the applications person coming in and teaching you how to use the console as part of that?

DR. PATTERSON: This does not specifically state who. It is just that you receive training in this new modality.

DR. KOPANS: Spending a day learning it? I think that is all right.

DR. PATTERSON: Well, that is basically 8 hours, a day, or less than a day as our meetings are.

Any problems with that?

[No response.]

DR. PATTERSON: Okay. Let's move on now to the exceptions. This is basically grandparenting.

I waited for you to make a comment, Dan. Weren't you the one that gave "grandperson" the other day? So I said grandparenting.

DR. KOPANS: Oh, grandparenting.

DR. PATTERSON: This is basically anyone who has met the interim requirements as already for the final, and there were pros and cons on this. I think the major one against it was that meeting this was really minimal standards, and they really wanted it tightened up a little bit more, but that was the only requirement on that.

Any comments? In other words, those that met the interim requirements should continue on is our feeling.

Okay. The second exception was on radiology residents. There were a lot of questions on this, the terminology, "the first allowable time." There were individuals that said this varies with different boards and, therefore, it should be spelled out.

They questioned about the last 2 years of all of the residents getting in their mammography training, and what happens if they do a nonmammography fellowship, do they need to go back and start over again in their 240 if they

have been out on a fellowship, say, doing an angio for the past 2 years.

The other question was if an individual in their first allowable time went and took their boards and ended up being conditioned, say, in mammo, where did they now fall under this, did they have to start back on ground zero.

Comments?

[No response.]

DR. PATTERSON: No comments.

I don't know. I just got so confused on -- yes, Joel.

DR. GRAY: I would suggest we try not to micromanage this. We are looking at cases where there may be one or two a year at most to deal with, and leave that up to the FDA.

DR. PATTERSON: This was almost my feeling about this. The more I read, the more comments and more confusion I had. I thought is there any way that they can individually look at the qualifications of an individual that has been in a residency that didn't meet this for some reason or another. No?

MR. SHOWALTER: I am not sure I understand the question.

DR. PATTERSON: In other words, is there some way to individually look at cases of an individual who takes their boards in the first allowable time? You have two scenarios. They said over here earlier, what if they failed in chest or what if they condition to mammo; in other words, now do they have to go back and meet the 240 reading in the previous 6 months, to start over again.

MR. SHOWALTER: We look at individual cases all the time as a result of inspection findings, typically, and they get controversial sometimes.

Very often, when we have a level one finding, that is, an unqualified person, that gets referred to headquarters. We evaluate the documentation ourselves. So it is not at all uncommon to look at individual cases.

DR. PATTERSON: Yes, Ed.

DR. HENDRICK: I think some of the confusion here is this phrase "the first allowable time" --

DR. PATTERSON: Yes.

DR. HENDRICK: -- which could be removed if you replaced that with "a time period from completion of their residency." So, if you kept the same clause but said "and to become appropriately board-certified within 1 year or within 2 years of completion of their residency," it would clarify this a lot.

DR. PATTERSON: Would you want it 2 years from the completion of their residency?

DR. HENDRICK: Well, the point is they have gotten their 240 interpreting examinations during the last 2 years of their residency. So you wouldn't want the time period to go too much beyond. It could be as much as 4 years, then, if you allowed it to go 2 years beyond the end of the residency.

So it might be reasonable to say 1 year after completion of residency because most residents take their boards during their fourth year, right?

DR. PATTERSON: Larry, you had a commen t? No?

DR. MONSEES: Most people take it right at the end of their fourth year, but fellowships are 1 to 2 years. So say, for example, somebody does neuro fellowship, which is the 2-year that I am thinking of, they will need that 2-year window.

Other people who do cross-sectional imaging fellowships or something else, it is usually 1 year.

DR. HENDRICK: But isn't this for the person who takes and passes their boards, regardless of what they are going on to in terms of a fellowship?

DR. MONSEES: They pass the initial requirements, as Larry said, before, and then, they didn't do the 240

during the last 2 years of their residency because they spent the last 2 years doing something else, a fellowship. So the question is, really, only why do they have to do the 240.

Isn't that right, Larry?

DR. PATTERSON: That is where the question is.

Yes, Larry.

DR. BASSETT: The 2-year period in addition to giving a little bit of leeway for someone doing a sabbatical or someone, that also takes into consideration, the person who is doing a fellowship for a year, so that they have 2 years to get the average of 40 cases per month in. So it also accommodates them, but I think the feeling was that if they do a 2-year fellowship, that is too long without doing mammography to allow them just to begin to do mammography when they finish it.

So, 2 years of neuro, if they want to do mammography at the end of that time, they will have to do it during that 2-year period, and there are methods to do that on their own if they want to, and if that is their desire, they can do that, but they should not be able to start all over again at the end of 2 years.

DR. PATTERSON: Does everyone feel there shouldn't be the 2-year gap after their board?

Yes, Cass.

MS. KAUFMAN: Larry, since that phrase, "the first allowable time," seems to be the area of confusion, do you have a suggestion on what might work in lieu of that phrase?

DR. BASSETT: I think what that phrase meant originally was that they should take their boards at the first opportunity after their residency, which would be June of their last year of their residency.

DR. PATTERSON: Well, there were different boards.

DR. BASSETT: That is right, the different boards. That is why the term was put in because different boards have different time scales.

DR. PATTERSON: Yes. So that was the reason for that.

DR. BASSETT: Right. For whatever board it was, they should take it the first opportunity that is allowed by the board.

DR. PATTERSON: Which was the first allowable time.

DR. BASSETT: Right.

DR. PATTERSON: That was the reason for the terminology. Maybe if that is just explained --

DR. HOUN: It is defined.

DR. PATTERSON: Yes, okay.

All right. Can I have the next one?

[Overhead.]

DR. PATTERSON: The reestablishment of qualifications, the way it reads is that they should do the 240 in the 6 months under direct supervision, and they need to meet up to that number as if they haven't had them, and if they didn't obtain the CME of the 15 hours, then they have to get enough of them to bring up that total in that 3-year period of the 15 hours.

There were only a few comments against that, and they said, well, there really should be a penalty on top of it all if they hadn't met those requirements, but there were, I think, only a couple of comments that made that statement.

The other group of comments that were made, again, was it was too prescriptive. Somebody or a group of them said eliminate the entire section, you don't regulate any other group.

They wanted to clarify what was acceptable, CME, very rigidly.

There were some comments that said don't change the interim rules, they are fine as they are, just leave them alone.

There were several comments that said the level of detail only makes it easier for the inspectors to cite facilities, et cetera, on not meeting certain requirements.

There was the individual who said that the interpreting physician should have their visual acuity tested every year. We know who that was. Specifically, they stated they really ought to be able to see those grid lines on the films, et cetera, and you don't know if they can unless they are tested.

The other ones, there were some comments -- and this was something that was talked about in the preamble, and there were some that was very much in favor of a practical examination or some way of determining that they were proficient in interpreting examinations, and if this ever came to be, then they were very much in favor of a periodic examination.

I don't know if there is anyone who wants to make any comments about the whole group of them. I guess the question is, have we gone into too much detail, and do we need to eliminate any of this.

Anything?

[No response.]

DR. PATTERSON: Okay. If you go to the last sheet, the questions, I think we have answered the second one which was should we drop the board, the 60 hours.

The first question is under the initial training requirement, I believe. Should all of the 3 months be obtained in an approved residency program or be taught by someone who teaches in a residency program or can this be from any interpreting physician? I guess we need to clarify what our feeling is about those 3 months of training.

We have beat on that. Did we allow either group? We said just the residency training or somebody able to teach in a residency program. Is that correct?

MS. KAUFMAN: And approved in.

DR. PATTERSON: And approved, okay.

DR. KOPANS: What kind of approved residency program? Radiology residency program or a pediatric residency program?

MS. KAUFMAN: No. It has to be radiology.

DR. KOPANS: Only radiology.

DR. PATTERSON: Okay. The last question was that performance-based standards could be used to replace these requirements as far as the initial requirements in the CME. What is the feeling about that?

Yes, Ruth.

MS. McBURNEY: I think that would be very difficult to assess, and I think it would be better to leave the rules as they are proposed for the CMEs and the qualifications.

DR. PATTERSON: Any other comments? I guess if there was one that was there, if we had a way of using it. I don't know.

Yes, Mike.

DR. LINVER: I think, ideally, it would be nice if we had a definite performance-based standard. Then we would, indeed, have a level playing field, and in lieu of that, I think we go with what we got.

DR. PATTERSON: Okay.

Yes, Ed.

DR. HENDRICK: The current board certification exams are, in part, a performance-based standard in the oral part of the exam. They are two separately things.

DR. PATTERSON: Well, the question was there were comments about the initial training and the continuing education numbers were sort of bureaucratic and could you replace that.

I think, unless you have recertification of your board, the individuals that were boarded 10, 20 years ago,

this would not meet this in any way, a performance-based standard, I would think.

Yes, Dan.

DR. KOPANS: I was just going to second, I think, what Mike said. Trying to make a test for people who are out of residency programs -- and I would also point out, radiology residency programs have a written examination as well as the oral examination that you have to pass, but subsequent to that, the American College of Radiology is trying to develop this kind of post-continuing education testing, and it is very, very difficult to do.

It might be a wonderful thing to say, but it doesn't exist, and it is very hard to do. Any one of these tests could be challenged, I think, by radiologists. I think this is the best you can do at this point in time.

DR. PATTERSON: I think we have covered all of this.

We will now move on to quality assurance.

DR. KOPANS: Is there a reason the mikes can't be left on?

DR. PATTERSON: No. You get too much --

MS. HEINLEIN: Can I ask a question? Did we say today that we were just going to revisit the qualifications

for medical physicists to see if there were any additional comments from anyone since it was on today's agenda?

DR. PATTERSON: We did that.

MS. HEINLEIN: I must have taken a nap during that time.

DR. PATTER SON: Did that, been there.

MS. HEINLEIN: Been there, done that. Okay.

DR. PATTERSON: We did both that and the additional clinic image review a week, first order of business this morning.

[Break.]

Quality Assurance

6 pmMammography Medical Outcomes Audit

[Overhead.]

DR. LINVER: You may all take out your books and turn to page 14881 for responsive reading. We are going to be talking about the medical outcomes audit quality assurance, third column, page 14881, (f).

I thought I would start by summari zing the basic general and specific comments that were made in this section.

I thought there were 262 comments until last night when I was about to go to bed and I pull out this addendum which had another 31 comments in it. So there were almost 300 separate comments in this section.

The general comments, there were exactly seven basic areas. The first which elicited the most comments, but also the most vague, was the idea that the audit requirement was, indeed, a good idea.

Of these 80-plus comments, one was unqualified approval. The others were qualified approvals of various types. There were various reasons that people didn't like the audit. They thought it was a bad idea because there was no proof that it worked. They thought it was a bad idea because it was too costly. They thought it was a bad idea because it increased the medical-legal liability. They thought it was a bad idea because the data were potentially misleading because of different patient populations and low statistical power.

Could you show the bottom part of this slide?

They thought that the audit section should include more of a precise definition of terms and performance standards, and lastly, the last general comment was that the audit responsibilities should be shared among other physicians besides radiologists.

You can see that the numbers were fairly substantial for most of these categories. So we had a fairly sophisticated group of respondees, I must say.

[Overhead.]

DR. LINVER: The more specific comments related to the section regarding the audit time table and that there really ought to be a change made in the audit time table.

Secondly, the audit should include additional data.

Thirdly, the audit should exclude certain data.

Next, there was only one comment, but I thought it was a very pointed one; that individuals who are interpreting more than one site should be allowed and encouraged, actually, to pool their individual data, his or her individual data to give greater statistical power to the numbers.

Lastly, there were comments regarding the corrective action section. As you can see, there were about five comments thought it was a good idea and about 11 comments that it was not for various reasons.

I thought I would go over the more specific elements now in the next slide.

[Overhead.]

DR. LINVER: I wanted to actually show the individual breakdowns for each of these comments.

The audit was too costly. About 28 comments were directed to the fact that they did not feel it was worth the expense involved since there was no hard scientific evidence that it does improve patient outcomes.

Next, about 10 comments specified that they thought that it added too big of a cost and paperwork burden, especially for small facilities.

Sixteen comments thought it was too costly because it required a computer and the hiring of additional people to really perform it well.

Two respondents thought it was too difficult to obtain outcomes data even on the limited basis in which the proposed final regs were written.

Lastly, there was too much work for the technologist, although this, admittedly, was written by the technologist's mother.

[Laughter.]

DR. LINVER: Do you want to discuss the individual areas as we go along, just to get a feel for the committee's feeling about each of these, or should we wait until we cover all of them?

DR. PATTERSON: You are moderating this. So you can do whatever is your preference.

DR. LINVER: I'll tell you what, I will just open the floor for any discussion about the issue of the cost of the audit and any comments that any committee members or guests might have. If not, we can proceed on and then discuss this later.

Gilda?

DR. CARDENOSA: I would just say it is too costly to ont do this.

DR. LINVER: Good point, I think one many of us share.

DR. CHRVALA: In terms of the need for additional staff and the need for a computerized system in order to effect this, that is not, in fact, the case.

They can do it, and I have seen it done with a shoebox, and it is nice if we can get it on a computer, but they have done this kind of work with very minimal amounts of paperwork.

The burden may begin with the tech, but I think it is important that the cost be spread over the entire health care community; that it is not just the tech that is collecting the information, but the physician and the surgeon all need to be oriented to the importance of this data and what it will tell us about mammography.

So it is not a sole burden on the tech. It has to have good community support, and it is doable. That kind of support is doable.

DR. LINVER: Dan?

DR. KOPANS: You know, one of the concerns expressed at small facilities is the small facility will have a much smaller problem, actually.

DR. LINVER: Sure. They are the ones who are more likely able to use a shoebox. Exactly.

DR. CHRVALA: The small facilities will have a problem because they won't have enough cases to come out with any reasonable data or any significant data.

DR. LINVER: Ed?

DR. HENDRICK: I wanted to ask Carole if you have any specific data or information about cost of doing the audit, either on a per-facility or per-patient basis.

DR. CHRVALA: Yes, I do have information on a per-patient basis.

For the system that I ran in Colorado up through the end of November, we had well over 400,000 mammograms and 300,000 and some women that we were tracking, and I was at a State health department and we did centralized tracking using paper forms as well as electronic data transmission. On an average, 85 percent of the women were normal, and we added in a piece of prompting return for reminders, a prompting return for rescreening. The cost for those women was less than a dollar. It was about 75 cents to get them back in, to enter the data in the system, and get them back in for their subsequent mammogram.

The 15 percent that had an abnormality, we had incredibly good compliance among the physician population because we

did a lot of PR, and we did not provide facility-specific data, but we gave them patient-specific data on their own patients, which was very useful to them, indicating that their patient had to come back for a return for -- I don't know -- a clinical breast exam or an ultrasound or whatever. The costs for following up the 15 percent of women who had an abnormality ranged between $1 and $2, and as the abnormality increased in severity, the cost increased. So, actually, it was probably $1 to $2.50 because, what would happen, a significant proportion of women were recommended repeat mammograms, and they were taken care of it by having a repeat mammogram. That was just an additional letter. So it just sort of increased that 75 cents up to $1.

DR. MONSEES: Just to understand this here, you counted zero dollars for women who had normal mammograms and only women with abnormal mammograms or is this averaged out over the entire screening program?

DR. CHRVALA: No. For women with the normal mammograms, it was 75 cents to remind her to return.

DR. LINVER: They got a "normal" letter, in other words.

DR. CHRVALA: It was range d between $1 and $2.50 to track a woman with an abnormal finding, depending, again, on the severity of that finding.

DR. MONSEES: This makes sense. The reason I am kind of doing a little mental calculation here, in our program, I hire a full-time person to track hours, which comes out of my budget because the facility won't pay for it, which is another interesting thing, who should pay for this, whether it should be the facility or the professional side. Somebody needs to be designated as responsible for this. So we have a full-time person. We do 30,000 exams a year. We have a computer system. It is not paperwork. It is done with a computer system. So that sounds about right from what you are saying.

DR. LINVER: There was also a presentation made at the RSNA last month that was a survey. Didn't Debbie Akita have this up? Of the Society of Breast Imaging Fellows, there were 46 fellows who did respond. It was fairly mixed, between academic and private practices, averaging about 16,000 studies a year.

The costs on the average were $20,000 for personnel, $12,000 for startup, $4,000 for yearly upgrades, $184 a week in mailing costs. This turned out to be an average, not counting the startup, of about $36,700 a year. This is just for the positive mammograms.

This is a broad spectrum. It is interesting, the range, for instance, of the cost for personnel was from $5 to $75,000. So it is a huge range.

In Carole's situation where everything is centralized, obviously, the costs can be minimized, but overall, the way it exists now in this country, I think it is a very, very broad spectrum.

DR. MONSEES: Right.

The number that I gave you was the yearly cost I pay an employee, plus benefits, probably over $30,000.

DR. LINVER: Yes, plus mailing.

DR. MONSEES: That did not include startup or mailing fees, et cetera, to send reminder letters, any of that.

DR. LINVER: So there is a real cost in dollars to do this. The big question is --

DR. CHRVALA: Particularly if you are not going to be doing it in a centralized fashion.

DR. LINVER: Right.

DR. CHRVALA: We had close to 60 centers participating without concerns about confidentiality simply because one o four PR methods was to emphasize the patient as a client with her own separate ID. The radiologist gets his or her own ID. The facility gets their own. Each physician,

surgeon or primary care physician, they all have their own separate ID.

One of the nice things about it was that we could track women as they move from clinic to clinic because they had a unique ID. It worked well because we printed reports on the basis of ID, and then, the lead physician who is in charge of QC/QA got their listing of radiologists so they could know.

It is interesting, when you did an analysis for a mammography center, you couldn't do a global analysis. If you had 10 mammographers, radiologists, if you had one or two outliers on either end, that group would look very normal, 15 percent abnormal, but when you looked at it by radiologist, the differences were -- yes, and between facilities, they were like that, too.

DR. LINVER: Yes.

DR. CHRVALA: So the data were really valuable for each center, and then they also got aggregate data that they compared themselves to, which was very, very much appreciated by the centers. They liked knowing where they fit into the bigger scheme of things.

DR. LINVER: I think that is a wonderful model from which we would benefit not only in terms of feedback, but also in terms of keeping the costs of doing an audit down.

Unfortunately, it is not what exists now. It is something I think we can strive to achieve. So that is one of the concerns that the respondents had.

The second concern listed was that they thought the audit was irrelevant because they weren't sure that there was any real proof that the audit improves outcomes.

I think we all know that any kind of feedback is going to give us a benefit. So, even though we cannot answer that with a true scientific trial, I think, intuitively, that goes counter to what we all feel about the use of an audit.

MS. SCIAMMARELLA: Mike?

DR. LINVER: Yes.

MS. SCIAMMARELLA: I am very concerned about when we analyze costs, how much a doctor costs, to send a letter to inform the patient. We never analyze how much is the cost of the doctors related to other costs and salaries. I think you have a sense as a consumer that we are protecting their profession more than to see what is the quality of the service in any line of health care related to the patient. I think we need to emphasize how much it costs to deliver good health care to the patient and know how much the hour of the physician costs to deliver the service who may be overweight -- I mean, high for different professions. So I think we need to balance that.

DR. LINVER: Well, there has to be a balance. There is no question, but the facilities have to be able to keep their doors open. They have to be able to pay the bills. So there is a real issue of cost that we have to consider here.

MS. SCIAMMARELLA: But when we are talking about a dollar and a dollar here, I mean, the legal implication is better service.

DR. LINVER: Yes.

Other comments under the so-called irrelevancy of the audit, they weren't sure that the statistics were going to be used in any meaningful fashion at this point. Again, one could argue, I think, that there is a value, even, in any kind of statistical analysis if it is used properly

Lastly, there was a comment that they felt that trying to obtain these data, sometimes you almost had to impose on the privacy of the patient. Again, I am not sure of the validity of those arguments, but those were made about the issue of irrelevancy of the audit.

The third area where they thought the audit was a problem for them concerned the issue of medical/legal liability. There were 28 general comments that they were concerned about -- actually, there were 39. There were 11 more that I found in the middle of the night last night. So there were 39 who were very concerned about confidentiality in general.

More specific comments thought that the audit needed medical/legal protection to assure participation of facilities.

The next comment, I think, is one that is pretty insightful, and I think we have discussed it before. Honest statistics may not be collected unless there is medical/legal protection because nobody wants their data to reflect negatively on them.

Next, there were two who commented that the FDA should address the issue of confidentiality and one that the FDA should mandate audit protection in every State. A great idea.

Lastly, the liability created on many levels was very real; that the data were subject to subpoena. They were usable in malpractice claims, and they could and would be used by third-party payers to award contracts.

So there were many issues on many levels regarding medical/legal liability. I know we have discussed this ad nauseam before, but if there are additional comments about some of these concerns -- Carole.

DR. CHRVALA: Yes. I just wanted to speak to a couple of them. In terms of the fact that they said there is no proof that it improves outcomes, again, looking at the Colorado data, women enrolled in the system were much more likely to

be diagnosed with early-stage disease, in situ or localized disease. They had smaller tumors, and there was a definite trend for downstaging compared to the State's population of breast cancer patients where about 68 percent were early stage.

We were up to 77 percent, and we had matcher our data base with the Cancer Registry, which had full-case ascertainment. So I think there is no question that it improves outcomes. The statistics obtained are meaningless. I think it is a training issue. It took me a long time to explain to physicians and to technologists what the information meant to them, and when that happened, they were eager for the reports and they started asking for special analyses for their own facility, which we offered.

The medical/legal liability issue, that swings both ways. When I early on started this project, I had a physician say to me, well, if I make a mistake, I don't want you to know it. Subsequently, we have had probably a number of cases, a dozen or 20 cases a month, where a woman has an abnormality and her physician doesn't know it because the report has been filed. The medical/legal liability doesn't become a liability in that instance anymore. We are really reducing their liability when you are doing this kind of an audit.

DR. LINVER: You are absolutely right. I can corroborate all of those things from our own practice in our own computerized reporting system we have used since '88. Our results have been quite similar.

The liability issue really does cut both ways, but I think the big concern, especially, is the discoverability, especially of negative kind of data, like false-negative kind of data. This is very scary to most facilities, and for good reason.

Dan?

DR. KOPANS: Well, that said, it is my understanding that these data are not actually being collected. What is required is that we look at them. I am not sure you want to necessarily put it in writing, but the data could disappear after you have done the analysis. That way, it is not an issue of someone just fishing for data unless FDA has somehow figured out how to protect this, which I doubt FDA has done.

DR. LINVER: Well, according to the proposed final rules, that is all that they are required to do, all facilities, and that is just show that they have a system for collecting information on all of their positive mammograms in place. They don't have to show the data. That is not a requirement.

It is sort of the foot-in-the-door kind of concept here that people are concerned that in their own facilities, once this begins to happen -- and there were several illusions in the preamble that there may be more coming -- that they are concerned that this will open up the door of discoverability.

DR. KOPANS: It is not just the medical/legal liability, though.

I think the first meeting I was at, we talked about this, and that is, the potential to compare one facility to another by, say, the media without taking into account all of the information that really goes into how many cancers you find per thousand women, for example.

DR. LINVER: Right.

DR. KOPANS: I think it is not something that should be easy to obtain for someone other than FDA knowing that it is being done.

DR. LINVER: Yes. Some of the other negative comments coming up relate to that, especially the fact that the statistics are so small for most groups that it doesn't have a lot of significant, but those are all relevant issues.

Penny?

MS. BUTLER: I am just pleased to hear your data, Carole, regarding the benefit derived from the audit.

We are always looking for what part of the regulations will provide a benefit. We have been talking a lot about cost, and here is a benefit. I think maybe this can be incorporated into the preamble perhaps in this section whenever the final regs come out.

DR. LINVER: In fact, it would be very nice. Are you planning to publish that? I think it would be very important that people see that in print so they will have a better understanding.

Larry?

DR. BASSETT: Carole, I do have to question, though. This is a highly motivated group of people who are being compared to another group, and I don't know if I have seen proof that it is specifically the medical audit that made their results better. That is the problem.

We have to have a study set up that specifically is set up to determine if that is a factor and have all of the other variables taken out, and not that I don't believe it is a good thing to do because we do it, and we do it with a belief that it is important for our practice, but to make a generalization that it is the medical audit specifically that differentiates this group when there are so many interventions that have taken place is what I think is

concerning me, not that I don't believe in it. I don't think that is proof.

DR. CHRVALA: Yes. I wouldn't argue with that.

Ed and I participated in this State-wide survey of the centers. So we have a sense of what they look like, both in the types of procedures they perform and frequency and their cost data, as well as a lot of data that refers to the physics side of things that Ed has looked at and trying to correlate that with image quality and outcomes like that where I think we are seeing some improvements.

The other issue, I guess, is that it is an education piece. It is educational. I mean, people are afraid of the numbers until they realize that they can be very informative and very helpful.

DR. BASSETT: That is not what I am questioning. My question is whether the study was set up, randomized so that you could really say this one specific intervention is what made the difference, and that is the only problem I have, not that I don't think it is great and education isn't great. I wouldn't be teaching otherwise, but I think from a point of view of these facilities and what they are going to be asked to do, in this preamble, if we are going to say that it is this intervention that makes the difference, I

think there should be undisputed scientific proof. That is the only thing that is missing in my mind.

DR. LINVER: That is a good point.

Dan?

DR. KOPANS: Yes. I would second what Larry is saying, but I don't think you have to go that far. I don't think you have to say that it necessarily absolutely improves outcome. I think it is part of a quality assurance program. We don't know that keeping the dark room clean actually improves outcome, but it is part of the quality assurance program. So I am not sure you actually have to even deal with scientific proof that the audit actually alters outcome.

DR. BASSETT: That is fine. I am just saying the statement has to be.

DR. KOPANS: I think you are absolutely right. The study we heard doesn't prove it, but what it does is it heightens, I think, the awareness of the radiologists who are doing this that it is a little different from everything else that we do, and that the level of intensity has to be a little bit higher for screening.

DR. LINVER: Could we show the next slide?

[Overhead.]

DR. LINVER: The next issue sort of alls on the coat tails of some of the others that the data can be misleading. Again, we have talked about the fact that since every facility is dealing with a slightly different population, and this will, indeed, be reflected in different audit numbers, that is absolutely true.

The volumes are so low for most practices that the numbers are going to be all over the place just because of statistical variation. This is a big, big problem in most practices when they are looking at their numbers because, even in a busy practice, each mammographer is going to find probably less than 10 cancers a year. So this is a real issue in terms of looking at audit data, and that is why the FDA has recommended not only individual data, but pooled data to try to get more statistical power to these numbers. I think these are legitimate concerns, but hopefully, they can be addressed.

Then, the next series of c omments was referring to the issue of the definition of the terms used. I think there is just a lot of confusion and concern out in the mammography community that they are not quite getting it about what the audit is about. They want more guidance, more specific guidance so that they know, really, what we are talking about and what they are talking about.

There were 15 requests for the FDA to define the methods for calculating audit statistics. Five requested that all audit terms be defined and tracking methods be defined more specifically.

Then, there were requests for FDA to set discrete standards of performance, and some even went so far to say that those who did not meet those standards should be punished in one way or another, sent to their rooms, various kinds of punishment.

[Laughter.]

DR. LINVER: There also were those who wanted FDA to set standards for a reporting system and that FDA should publish performance standards so that the lead physician can have some kind of reference by which he or she could take corrective action, which I think is a legitimate concern. We will get to that in the corrective action section that this does have some relevance to that.

I think many of these concerns are legitimate, especially the idea about the fact that we really don't have or can't apply standards to something that is so variable from one practice to the next.

The audit statistics, again, the FDA is not requesting anything more at this point than just the review of positive mammograms. Certainly, FDA, I don't think needs to write an

entire new book on this, but could give reference to articles and literature that exists at this time.

The sharing of audit responsibilities, it is a really nice concept. I am not sure we can ever really bring it into anything more than that at this time.

I think all of these concerns were legitimate that the referring docs really should be involved in notifying radiologists for the follow-up of positive mammograms. That would make the radiologist's job a heck of a lot easier. It is going to be very hard to do, of course.

I think this is doable. The referring docs must have a knowledge of the regulations and what is required for the audit.

There were those who asked that the surgeons be involved in the process; that they should provide biopsy reports and should actually be audited in their own practices, and that the pathologists be required to issue a report to the radiologists who provided the specimen image.

So I think, again, these are all legitimate kinds of questions to ask, but again, I will throw this open briefly to the floor. Are there strong feelings that FDA should be regulating in these areas as well?

Betty?

DR. PATTERSON: If I remember correctly, we discussed this previously, and it comes back to the fact that MQSAS regulates the facility and really has no jurisdiction over the individual practitioner, the surgeons, the pathologist, et cetera.

MS. SCIAMMARELLA: Elizabeth, I think you are right. I was one of the false-negative ones.

The issue is like in an institution. You track mortality issues and how you rate institutions. I think the same thing can be evaluated, and maybe we agree with Barbara that we need some epidemiologists to get involved and take courses. We need to track the performance of the member who participates in an institution.

From the consumer perspective, there needs to be a way to have accountability for how people track. I mean, to evaluate good places and bad places. That needs to be taken into consideration.

DR. L INVER: A team approach would be nice. It would be nice to get everybody on board, but again, I don't think the FDA can regulate.

Yes.

DR. CHRVALA: Just a real quick comment here. The surgeons actually were in my environment asking to be a point of

entry into the system after a few years because they wanted their own data back on their own performance.

I also think that this is such an ideal arena for what the information can say in a non-punitive fashion. So that, if the physicians are getting the information in a nonregulatory manner -- and I realize FDA is a regulatory agency, it can, I think, do things in a way that encourages the mammography centers and the physicians to see this not as regulatory, but as educational and a way for them to reduce their liability because of missed cases, lost cases, that kind of thing. I think that is doable.

DR. LINVER: Change in audit time table. These are more specific concerns, and they relate to various sections within this part of the regs.

The audit tim e table, as it was originally described, I think is listed under (3), frequency of audit analysis. An initial audit shall be conducted no later than 12 months after the date the facility became fully certified. Subsequent audit analyses shall be conducted at least once every 12 months from the date of initial analysis.

There were several comments made, about 30, that, really, the audit period should end at some period of time, 60 to 12 months, prior to the performance of the audit itself.

Indeed, I thin k there are good reasons for that. First of all, if you are going to look at false-negatives, you have to allow 12 months time to intervene, at least to start to get good information on the false-negatives.

Secondly, if you do allow for an interval, I think the collection becomes a lot more complete. So I think this actually is a very good suggestion, and when we get to the questions at the end, I will bring this up again.

One physician thought that the lead physician ought to be reviewing data every quarter. That was that person's opinion.

In addition, people wanted additional information collected for a variety of reasons. Six respondents thought that all abnormals should be tracked; that is, not only the birads, 4's and 5's, the probably malignant and almost certainly malignant, but also the birads at level zero which needs additional evaluation and the level 3, the probably benign finding, 6-month follow-ups.

Again, even these people, they were mostly people from the Breast Cancer Consortium who responded in this way, and they were well aware of the problems of trying to get these additional data in some non-organized fashion. So they, again, thought that FDA should encourage this, not mandate it at this point.

There were five respondents who felt that we should track and try to obtain all false-negatives. There were two who felt all measures of sensitivity, that is, cancer detection rate, the percentage of minimal cancers, the percentage of node-negative and -positive cancers should be tracked, as well as all measures of specificity, that is, recall rate, positive predictive value and, within that, positive biopsy rate.

There was one kind of vague comment which I really didn't understand where they said that we should collect all evidence-based, outcome-oriented, quality assurance measures, and they kind of left it at that, I guess, leaving it up to our imagination.

There was a very good comments made that we should make it an effort to get all pathology reports, especially if you work within one institution or two institutions where you can easily access these as a means to find any and all false-negatives which may exist in that hospital population, patients you may have done a mammogram on at some point and it was negative and now the patient has returned back and has had surgery which showed a cancer.

So there is a source available for false-negatives that ought to be pursued, and I think that is a very good suggestion.

There were respondents who thought there were specific things that should be excluded. Five respondents thought that false-negatives should not be included in an audit because it was -- in fact, there were actually eight, five plus three -- that it was much too burdensome. Nine respondents felt that the false-positives really should not be emphasized because they weren't as important as some of the other demographic data. There was one respondent who felt that demographic data should not be included in the audit.

Corrective action. This section is under (4), where it says the reviewing interpreting physician shall designate -- the facility shall designate a physician to review audit data at least every 12 months. The individual shall record the dates of the audit periods and shall be responsible for identifying issues and analyzing results.

Then, it said notifying, which we in April decided to change to communicating with the other interpreting physicians of these issues and results and ensuring that necessary corrective actions are taken and documented.

This is the issu e that was raised by these respondents. Five supported this concept that it enhanced accountability. Eleven opposed it; nine, because they felt that performance monitoring and correction actions were not presently

definable, and there were two opposed because the definition and enforcement, they didn't feel were possible.

I think these, again, are legitimate concerns because, again, we don't have a performance standard by which these things can be measured. So it is difficult to ask somebody to take corrective action without really having a standard by which they can measure that action. So I think this is a reasonable concern on the part of these individuals.

Then, there was the one comment made about if an individual reads it more than one site, that that person should be encouraged to pool the data from each site, to collect their individual data, and I think that is an excellent idea as well. There was one comment about that.

Next slide.

[Overhead.]

DR. LINVER: So those were the comments.

What I tried to do here was address my own feelings about what the recommendations should be, and I will open up the floor after I go over my suggestions.

These address the four questions, slightly different four questions from the ones I am usually thinking about.

Anyway, the first question was, should we mandate more specific statistics, and my own personal feeling is at this point in time, no, we should not for a variety of reasons,

because of the costs, because of other difficulties in trying to collect these data, because we need more proof to convince facilities that this is to their advantage to do a more extensive audit.

I think at this point in time, there are real concerns about the medical/legal liability that we have to be sensitive to, real and imagined, and until such time as we can do more about that, I think there are going to be real issues that we are going to be facing in this area.

The second question was, should the section read that a physician should be asked to obtain data at least on all examinees regarding at least the positive mammograms. I think absolutely, the words "at least" should be added. And in addition, that we should encourage the collection of other information, including review of all identified cancers.

The third question, should we change the time period after the audit ends for collection and analysis, the 6 to 12 months, and I feel yes. Probably, 12 months is reasonable, especially if we are really going to start to get good numbers in each category, especially the false-negatives. So I feel that it is very reasonable to change it and have the 12-month hiatus.

Lastly, the last question was, how can the FDA encourage more in-depth audits, and I think the most direct way is to somehow help us get some legislation passed that can really truly protect audit data.

Those were my responses. Now I will open it up to the floor for any additional discussion.

Larry?

DR. BASSETT: Mike, I was just going to comment that in California, we recently had a court decision. I think it was the California State Supreme Court that determined that yes, the California board could go into quality assurance records for the hospitals. It was just a recent decision that was, unfortunately, for quality assurance record protection. It went the other way.

I don't know if the FDA or any of the other groups are doing anything to try to protect this specific kind of data, which may be specific enough to separate it from that other data, but we were all sent a letter. Everybody in our hospital was sent a letter in terms of this change. That used to be protected data in California. Apparently, it no longer is within the hospital, just as of a few weeks ago. So this is still a problem.

DR. FINDER: Let me just at least partially answer that. In the Act itself, there is a section on research grants, and

part of that has to do with limiting access and maintaining confidentiality of all stored data.

Now, that, I have been informed, was specifically taken out of the realm of FDA. This is going to another organization for a grant. So that is going to be looked into.

I have also been informed that NCI has voluntarily agreed to look at some of these issues, not specifically this one just yet, but we are trying to encourage them to do that, but FDA specifically was not involved in this aspect, at least.

DR. LINVER: So that was not a part of the legislation.

DR. FINDER: This is something that is granted to somebody else.

DR. LINVER: So FDA was not held accountable for this portion.

MR. SHOWALTER: Let me just add to that, that FDA is not in the habit of trying to get legislation passed either.

DR. LINVER: I understand.

I think this is something that we all within our own organizations, since there is an awareness of the problem, should attempt to try to get action within our own organizations.

Yes, Carole.

DR. CHRVALA: I think one of the strongest factions that we worked with were consumer breast advocacy groups that really

pushed this forward with women saying we want to go to a site that offers this as a service to me because I know I am going to get a reminder letter and I know that I am going to get tracked and followed up to a great level of detail.

So I think it is not going to come from FDA. It is going to come from grass roots groups, consumer advocacy groups, I think, that will make this occur much more quickly.

DR. KOPANS: How are you protecting the data in your database from medical/legal discovery or from a reporter who wants to look at all the different sites?

DR. CHR VALA: Well, in Colorado, we had legislation that had the caveat that our data were not available for consumer utilization, so that you couldn't give out case information.

DR. KOPANS: Yes. I think that is one of the critical issues.

What Larry is saying now in California, for example, is that everything is discoverable. There is nothing that is protected. I fully sympathize with you in wanting to know that there are data to show that you are going to a good quality place, but the problem with data such as these, if they are not very etherial -- and I, quite frankly, think they should disappear as soon as the audit is done -- is that they are going to be misused.

Everyone is trying to use the medical/legal system to make money, which means that people who have maybe a real justification are unfortunately at a disadvantage.

I would just say that I think the audit is a reasonable thing to do, but to make it any more discoverable, I think, would be a major mistake.

I have got one other question, Mike, b efore I give up the microphone here, and that is, it doesn't seem to me that it says that the audit -- maybe I am misreading it -- has to look at a 12-month period at the end of the 12-month period. It is just saying every 12 months you need to do an audit. I would actually delay, as you are saying, and I would look with a 6-month delay so I can catch up on the cancers that maybe haven't gone to biopsy at the end of the period, but we recommended it, for example. So I am not sure you actually have to change that specification. People can do it however they want, it looks to me.

DR. LINVER: That is a good comment. Thank you.

DR. PATTERSON: I think I wanted to emphasize that I feel comfortable if we go and FDA agrees with NCI to see what direction to move, what is in the research arena. Here, we need to see the demographic part, too, the race and ethnicity and what had happened and in what region. So there is a lot of information that I would feel comfortable

if FDA will not regulate about this, but discuss with others, CDC and NCI, to see what direction to go.

DR. LINVER: Larry?

DR. BASSETT: Yes. I just want to make one point, and that is that I am getting a little confused. We are talking at one point about tracking patients who had positive mammograms or who had a zero so that they need additional imaging and they need to be followed up. Then, we are talking about medical audit. I think there are some differences here.

When we are talking about tracking patients who had a positive mammogram, I don't mean to in any way infer we shouldn't be doing that as a regular practice, or those that we gave a suspicious or highly suggested malignancy category to that we should make sure that they get to a surgeon in a month or they get a biopsy.

In addition, a patient with probably a benign finding, they should get a 6-month follow-up. We should all be doing that tracking.

I think when we are talking about medical audit here, we are talking about doing a retrospective review and see if there were false-negatives, going back and looking at the mammograms on the ones that were positive, looking at

sensitivity, calculating specificity, positive predictive value and all those things.

So, when I am saying I am not sure we should require that kind of medical audit on these facilities at this time, and that has a lot of problems in here, in no way am I saying that we shouldn't be continuing to follow the patients who were positive and make sure they get their follow-ups done and their biopsies done and so on. I am hearing those two things mixed in the discussion, and that is bothering me a bit. Really, I think there are two different things going no here.

DR. LINVER: There really are.

DR. BASSETT: Tracking and monitoring versus doing a medical audit may be different. I know that they both can be combined as well, but they shouldn't be seen as the same thing in the context we are currently talking about, I don't think. Do you understand what I am saying?

DR. LINVER: Yes.

I think part of the problem is , obviously, we all want to get as much information as we can, and in the preamble, there is, I think, a very good discussion about some of the benefits of doing a complete audit.

DR. BASSETT: What about follow-up monitoring? No one is questioning whether that should be done, right?

DR. LINVER: Right. That is what the regulations specify, that we do follow up with positive mammograms only.

DR. BASSETT: Which means we are checking to see that the 6-month follow-ups get done and the biopsies get done.

DR. LINVER: No. It is only the 4's and the 5's.

DR. BASSETT: Okay, only the 4's and 5's. Well, that is the one thing I would think you might want to expound, but that is different than what we are talking about, calculating numbers that we are going to put somewhere and compare one to another and all that.

DR. LINVER: I think it is a continuum. We are only beginning. The legislation allows for a good first step, that is, at least tracking those cases that we think are going to be cancer. The audit, as we can envision it, can potentially have a much bigger role in everyone's practice, but we are certainly not there yet, nor can we even begin to even think about requiring those kinds of things without all of these other ingredients in place.

DR. KOPANS: In a sense, though, the audit that is in here is doing what MQSA wants --

DR. LINVER: Yes.

DR. KOPANS: -- and that is encouraging the continuous improvement, if you will, of the quality of the mammographic service.

DR. LINVER: Yes.

DR. KOPAN S: The issue of comparing data around the country, that, I think, is very interesting and could also have some benefit, but what is, I think, set up in here actually very nicely is that radiologists need to look internally, look at how they are doing, understand who they are sending for biopsies and what the results are. That is a major improvement, I think, in what most practices ever did.

DR. LINVER: Oh, it is huge improvement.

DR. KOPANS: I am not sure. It may be the first step. It may be the last step. Until there is protection from discovery, it is suicidal to be providing data. You will end up closing down all of the mammography facilities in the country by providing data out of context and out of control.

DR. LINVER: Yes. The better you are at obtaining the data, the more liable you are going to be.

DR. KOPANS: Again, I don't see the problem with this. You do the audit. It is done. It is over. You have learned something from it. Hopefully, each radiologist has taken something from it, and then it is gone.

DR. LINVER: Go ahead.

MS. OAKLEY: I wanted to respond to what Carole said about the consumer groups. As you all know, I represent the National Breast Cancer Coalition on this panel, and one of the things that we are currently very involved with through the National Action Plan on Breast Cancer and the Genetics is the privacy issue. It is a very big issue.

So I think what you are saying is correct in that I certainly in the capacity that I have had appreciate what you are saying. In my former employment, we were involved with a multidisciplinary panel of physicians who kind of fit all the categories up here, and we were going back and we tracked and looked at pathology reports and took them back to the radiologists, and again, a very small practice compared to some of the larger ones that you all have, but we were trying to do it that way. The medical audit, the legal ramifications were what scared everybody away.

So I think that I hear what you are saying, and I think that there are thousands of other women who will hear the same thing because we already are very actively involved in the genetic piece of it as far as privacy issues, and I think it is just going to spill over into other things.

So, again, any part that the large organization that I represent can play in working -- again, the FDA is not used to going to the Hill. The coalition is used to going to the

Hill. So I think that whatever part we may be able to play in that, that we would certainly want to play in that, and the Komen Foundation and Gilda representing the Komen, that is another huge organization. Again, there are lots of us who will help in this issue.

DR. LINVER: Thanks, Marsha. I think that is the way we need to go, to work together.

Yes.

DR. FINDER: It is now 7 o'clock. We have five more topics we are going to discuss to night.

DR. LINVER: Okay. I have one more slide. Real quick, real quick. These are just a few other specific issues that I think ought to be addressed.

I think the idea t hat came from this one individual about if they do screen at more than one facility that they should be encouraged to pool their data for their individual audit should well be addressed by the FDA in the regs and probably should be.

The only other item that I wanted to mention is the issue of this corrective action, and I mentioned this before, but I think it may well be a good idea for the FDA to reconsider the language because there really are not standards. There are no unequivocal performance standards by which FDA can truly set and allow people to compare themselves to, and I

think the language should be changed to read that perhaps instead of saying corrective action taken, a document should say, "In communicating these issues and results to other physicians, documentation of such communication is required."

To go beyond that, I think, is going to add a great deal of confusion if we don't get more guidance, which I don't think we or the FDA can give at this point, but what specific performance standards they should be measuring each person in the group against.

That is my final recommendation.

Yes.

DR. CHRVALA: I have a comment. I will make this very brief. One of the things that we found that we had to do in Colorado when we were running this program was separate out the birads categories that included conclusions, and we had to have separate interpretative categories, including the five, up to highly suspicious, but we didn't always have radiologists saying highly suspicious, go to biopsy. That is going to be another issue.

In the real world, radiologists will say this is highly suspicious, but bring her back for some additional imaging or something like that.

DR. LINVER: Yes.

DR. CHRVALA: That presented a huge problem for us.

DR. LINVER: Well, hopefully, in the regs, in the proposed final regs, we are asking each physician to designate each case as a 1 through 5 in their final decision. So they really have to put their name on the bottom line with the specific numbers.

DR. CHRVALA: Wh at they did was, then, use the zero category all the time.

DR. LINVER: I know. There are always going to be problems. Okay, thank you.

Any other comments?

DR. KOPANS: I would just ask, if you use the zero category, you still have to bring the patient back and get a final category.

DR. LINVER: Yes.

DR. HENDRICK: I would just second your recommendation, especially the idea of polling data on individuals if they interpreted more than one facility because that is really what is going to be of greatest benefit to the individual and to help them improve their interpretation.

DR. LINVER: Thanks, Ed.

DR. PATTERSON: Thank you.

I just want to make one slight correction. Dr. Finder lied. There is only four more.

DR. FINDER: I was trying to scare you.

DR. PATTERSON: Moving right along, Rita. This is the section of the examinee with breast implants, and this is 14881 to 82.

[Overhead.]

Mammographic Procedure and Techniques for Mammography of Examinees with Breast Implants

[Overhead.]

MS. HEINLEI N: The good news is there is only five overheads for this, and Margaret is still bailing out her house and sends regards.

To start with, I just want to cover 10 general comments that came in, and then we will go through the specifics.

Six people stated that the facility should have the option of providing mammography for examinees with implants.

One person said that low volume will affect the quality of implant imaging and, therefore, they should be able to turn these women away and send them to a facility that does more implant imaging.

One suggested a minimum volume for facilities that do implant imaging to make sure that they maintain their skill level.

One suggested limited the requirement to only having a written policy regarding implants, women with implants.

One strongly opposed the mistaken idea that all facilities are required to image examinees with implants. They were just some general overall comments.

Let's go to the requirements and take them apart. The first one is that each facility shall have a procedure to inquire whether an examinee has a breast implant at the time that it is scheduled.

So we will go to the next slide.

[Overhead.]

MS. HEINLEIN: Interestingly enough, 133 comments were against this. I have to say I was surprised. 133 comments against it and 13 for. Of those that were against it, 50 commented that is disregarded privacy concerns for the woman.

Four said that it was not needed because it was not necessary to have an on-site physician. So I think they thought that you would only ask to be sure whether there was an on-site physician there.

Ten just plain said it wasn't necessary to ask.

Three said that you need to inquire, but you should not regulate as to when it should be asked.

Five said it was not even necessary to ask if you have trained technologists present at all times. Then, it is not

necessary to ask. The patient can just arrive, and you would easily be able to do her implant.

Twenty-nine said that the proper time for inquiry is during the mammography examination, during the taking of the history.

One said that the patients do not like to be asked if they have implants from either an aid or a receptionist. They also said a nurse. Instead you should allow time for occasional implants in the daily routine, allow additional time, and then ask during the history.

The reasoning behind that was if you have additional open slots in the routine schedule, then if a patient with implants did arrive and it took a longer time, you would be able to pick up any overflow during those open slots.

I have to say I was quite surprised. I mean, I just thought that everyone would want to ask at the time that the patient is scheduled to know that if the patient has implants, it would take longer than a routine screening exam, and I was happy to find the 13 in the sea of 133 against.

Any comments from the committee?

Dan.

DR. KOPANS: Yes. I think, unfortunately, this got by my initial review. We just published an article, actually, on

the whole issue of implant imaging, and I guess you will get to the physician on site. That is absolutely unnecessary.

MS. HEINLEIN: That opens up a whole new bag of worms.

DR. KOPANS: Okay. Well, there is no scientific support for it, and the science says you don't need a physician on site. In terms of inquiring and scheduling, Barbara and I were just talking here. I can see that in terms of your own organization, that you may want to do that because of what you are saying, it takes longer to do someone with implants, but as to making it a requirement, absolutely not. We don't inquire about implants.

We just got through saying the technologist has to be trained in doing implant imaging. When they come to our screening facility, we find out they have implants, we do the appropriate views.

You may want to schedule a double slot. So you may want to ask ahead of time, but it should not be mandated.

I guess this is just on the inquiry part.

MS. HEINLEIN: That's all. That's just that.

DR. MONSEES: The inquiry part, I think maybe it shouldn't be a requirement, but it should be an option, and I think that it is very important, for example, with vans where there is batch processing or some other reason that you would be ill-prepared to do an implant patient.

In terms of privacy issues, I think that you are going to have to ask sometime. You might as well ask up front, particularly if you are scheduling screening patients in 10-minute slots. An implant patient walks on, that patient is going to be equally or more disturbed to find out that her exam is much more time-consuming.

At that point, she is going to be in the room. It may be embarrassing for her, for example, if it is at a corporate screening that she is there for half an hour instead of 10 minutes.

So I think that it should be not only allowable, but in particular situations where it is going to take more time and that it may be embarrassing to the patient, that it should be something that is encouraged at that particular site if it is going to present a problem to them to handle that patient on-line like that.

DR. KOPANS: Can I just respond quickly to that?a

MS. HEINLEIN: Yes.

DR. KOPANS: I mean, that is a logistical issue, again, that should not be mandated by legislation.

I think the issue of vans with batch processing, just to complete the topic, is that it is a manual technique with the implant in the field of view, and the technologist in that situation would not be able to check her films and make

sure that she had the proper manual technique. So that is really the only situation that I can think of where you would need to know ahead of time that someone has implants, but for regular nonmobile facilities where processing is done at the time the patient is there, there should be no requirement that you ask. There is no prohibition either.

MS. HEINLEIN: Ruth?

MS. McBURNEY: For those facilities where the technologist is not qualified to do implant imaging --

MS. HEINLEIN: They have to be.

MS. McBURNEY: Does that go back to -- all technologists have to be qualified.

MS. HEINLEIN: They all have to be.

MS. McBURNEY: Then all facilities -- well, I just thought if there was any facility that was not capable of doing it for some reason or another, they would need to ask in their protocol to be able to refer them to someplace they could.

MS. HEINLEIN: Right.

Elizabeth?

DR. PATTERSON: I agree. It is nice to know ahead of time that you are going to have a patient that is going to take longer to do than the normal screening study, but on the same token, do you ask every patient that is getting ready

to come in, well, are you kyphotic, do you have a disability, are you able to do blah, blah, blah?

I mean, there are regular patients that take a longer period of time for whatever physical reason that they have. They come in with Parkinsonism and it takes longer or what have you. So I think for that, you have to just build into your schedule a safety valve of time type of thing.

The reason why I am saying this is because, recently, we had a patient who got very, very indignant regarding this because not even her husband knew that she had implants, and therefore, she didn't feel that this should be public knowledge ahead of time type of thing.

I guess for privacy issues, this probably is an invasion of privacy. Everyone says, oh, here comes that implant patient.

MS. HEINLEIN: Marsha?

MS. OAKLEY: I had just asked Larry before I asked this question to you. In our facility, any time a woman had an implant, it was an automatic diagnostic. The chairman of mammography would have had our heads.

I see you over there shaking your heads, but in the facility in which I worked, it was an automatic diagnostic. It was an automatic question asked when she registered, and I would have had my head off had we not done that.

DR. PATTERSON: Larry?

DR. BASSETT: Let me just note that Dan's head was going in one direction and Barbara's the other. As we all know, even as we discuss this with this diagnostic standard, there is not a definitive bottom line on this. So there is a difference between facilities.

So maybe it should be optional, but we certainly find it is helpful to the patients. Other patients don't like to wait either when someone takes longer. At least in our community, the women who come are very busy. They are upset if they get half an hour behind because they have got appointments, they have got to get back to work, they have got to pick up the kids. They have got a lot of stuff to do that they are very busy for. So I think scheduling and getting it done officially is an important quality assurance activity, to tell you the truth.

I am not saying one way is right and one way is wrong. I am just saying there is a difference.

DR. KOPANS: That is, again, what Elizabeth was saying. There are different issues that have to do with getting people --

DR. BASSETT: But this is one you can.

DR. KOPANS: I am not saying you can't do this. I am not saying that you can't make it a diagnostic study.

DR. BASSETT: Right.

DR. KOPANS: From a scientifi c perspective, the only study that I am aware of is the one we published that showed there is no increased recall rate for women with implants done in a screening setting, and so there is no scientific reason to do them as a diagnostic study.

That doesn't mean you can't. In your practice, you happen to feel that way, but you shouldn't legislate a diagnostic physician on site.

DR. BASSETT: No, that has all be discussed with. It is over with. It has been decided that is not required before at this meeting.

DR. KOPANS: Asking a head of time --

DR. BASSETT: Right.

DR. KOPANS: -- should not be legislated. It may be that is the way you want to handle it in your practice to make things go more smoothly, but it is not something that should be in legislation.

MS. HEINLEIN: Well, I certainly think that based upon the public comment and the comment from the committee, the FDA understands that this should say that it is optional to have that procedure or take it out or something.

DR. KOPANS: They may w ish to have a procedure.

MS. HEINLEIN: Right, may wish to.

All right. Any other additional comments on that?

[No response.]

[Overhead.]

MS. HEINLEIN: All right. Next, except where contraindicated, those patients with breast implants shall have mammographic views to maximize visualization of breast tissue on optimized breast cancer detection.

Interestingly enough, of the 474 comments concerning implants, only five of them addressed this issue. Three said that yes, you should absolutely do displacement views and that we should indicate specifically in the legislation that you should do displacement views.

One then said, well, some cannot be displaced, so mandating any type of view would result in increased radiation.

One just said minimum standards should be set.

I think in lieu of the number of comments based upon the fact that 474 were received, I think that the way this is worded right here seems to cover it, and I think it leaves the flexibility to the facility to do what they think is best for that individual woman.

Any comments on that?

[No response.]

MS. HEINLEIN: Okay, next.

[Overhead.]

MS. HEINLEIN: Oh, I'm sorry. Ed?

DR. HENDRICK: I think that gets at what the enabling legislation really wanted, which is, and I am quoting, "standards relating to special techniques for mammography of patients with breast implants."

MS. HEINLEIN: Right. And you think that is covered in what is stated there.

DR. HENDRICK: I think so.

MS. HEINLEIN: Yes, I do, too.

Next is the one which, by fa r, received the most comments, and that is requiring the presence of an on-site physician. 313 were against this. Five were four.

Forty-seven said that rural sites will just not be able to staff an M.D. on site. Interestingly, 17, then, said, well, not only rural sites, but other sites do not have M.D.'s sometimes until the end of the day if they are rotating through different facilities.

Thirty-five said that this was redundant; that once a trained RT's performance is monitored by assessment of image quality. So, therefore, it is not necessary to have an M.D. on site.

Fifty-eight said that it is the technologist, not the physicians that are experts in positioning and performing exams.

Yes?

MS. KAUFMAN: I am sorry to interrupt you, but it is getting really late, and I think we have gone over this one ad nauseam. The consensus is that this ought to be taken out. So I just wonder if we could move on. Do we need to hear all the comments?

MS. HEINLEIN: Okay.

All right. Interestingly enough, let' s just look at the five that said that there should be someone on site.

The next one.

[Overhead.]

MS. HEINLEIN: Those that did, all they said was you should have one on site.

One person said large percentage of additional views are needed, and then you can just see the others, but I think that, considering the public comment, it is easy enough to say that that section can be deleted.

Okay, the end. Do I get a star for a short time?

[Applause.]

DR. FINDER: I think you also deserve one for the fact that your package that was mailed out to you was, by far, the heaviest. It was 46 pounds of materials.

DR. PATTERSON: Yes, Joel.

DR. GRAY: A procedural question. Was dinner ordered for tonight or tomorrow night?

DR. PATTERSON: It is coming.

DR. FINDER: It is supposed to be here any minute.

DR. PATTERSON: It was supposed to have been here at 7 o'clock.

DR. GRAY: Okay.

DR. PATTERSON: So what I am going to do is I am going to move onward, and when it comes -- please go find out what happened to it. I am starved.

I know. That is on the record, right?

Anyhow, the next section that we are going to is Carl. Where is Carl? Oh, there he is. He is going over definitions. This is on page 14868, from there to 70.

Definitions

DR. D'ORSI: We are only going to cover the definitions that comments were made on, and I would like to start with the one that received the most letters, which is mammography 900.2(s). As you can see, it is a little crooked over there.

Let me just quickly give you a lit tle history of why there were so many responses to this definition. If you remember, back in April, we discussed the possibility of deleting the

exclusion of stereotactic core biopsy in the definition of mammography.

What that means is that if we delete that, people developing and producing films in the process of doing a stereo core biopsy would have to have all of the qualifications of an interpreting physician, and this as we discussed it was deemed a good idea and this was the recommendation made in April.

As you can guess, there was a large amount of discussion and letters that were received concerning the deletion of this statement. There were 139 letters, and I am just going to summarize, as you see up there, what the pro letters stated, which the pro in this case is meaning that there is no change and keep this as a deletion.

Surgeons can read mammograms. There is no big deal in interpretation. Surgeons are used to dealing with breast cancer. Therefore, they should do the core biopsies without any other requirements.

The patient access would be limited. This was a semi-valid reason, I thought. Many letters stated that radiologists just didn't want to do this procedure in their area, and they were the only personnel who could do this procedure.

So those were basically the comments, summarizing the comments, dealing with the pro.

If we just pull that thing up a little bit, you can see the letters, the con letters which favored deletion. Some of the statements were stereo is the most difficult type of imaging. If this is not addressed now, we will have another 10 years before we can address this under regulations.

If we can go to the next slide.

[Overhead.]

DR. D'ORSI: If we look at the summary here of what the --

DR. PATTERSON: Carl?

DR. D'ORSI: Yes.

DR. PATTERSON: Maybe we should stop for just long enough for them to distribute the food.

DR. D'ORSI: That is fine.

DR. PATTERSON: I think we have got everybody looking to say when is my food coming, and this will answer Joel's question about what was it ordered for.

[Break.]

DR. D'ORSI: Let's continue. We will put those lights on. We will start with the summary. The 69 letters which favored deletion of that statement, which would mean that all people doing stereo would have to have the requirements of an interpreting physician, said that interpretative skills are extremely important for targeting the lesion. Interpretative skills are necessary to recommend follow-up

of what comes out of this core biopsy, and many letters were worried about self-referral from surgeons.

It is interesting that the surgeons, three of them included articles written in surgical literature about their positive predictive value for core biopsy which was 9 and 10 percent, and I found that very interesting.

Ten of the letters, interestingly, out of that conglomeration of 139 mentioned that a cooperative approach would be best; that is, that both the interpreting physician and the non-interpreting physician should be or could be involved in stereo core biopsy.

A little bit of background before I go to discussion. The ACS and ACR -- the American College of Surgeons, not the American Cancer Society -- and the ACR have been discussing the stereo core biopsy together, dealing of issues of when it should be done, technique, et cetera, and also, recently has a meeting at the RSNA concerning who should do these procedures.

In that discussion -- I hope Larry is here -- in that discussion, it was at least recognized that the best situation would be a combined situation in which an interpreting physician and someone else, i.e., a surgeon or anyone else, actually, would both be involved in the stereo core procedure, and if that was not the case, apparently the

surgeons or at least the representative, David Winchester who is not here tonight, felt that if an interpreting physician was not involved that the person would have to have the qualifications of an interpreting physician.

So let me open it up to the floor now. The choices are as follows. Delete it, which means that everyone who does stereo would have to be an interpreting physician.

Now, remember this, and this was some of the things that other people worried about, the other side of the coin, if that is the case, programs may be forced into training surgical residents, et cetera, for mammography so that they could fulfill this requirement to do stereo core biopsy, and you might be inundated with requests to train people out of your residencies. That is the negative part of the coin.

The other choice is to leave it alone as it is and hope that the FDA addresses this before the ice age comes. I don't mean that negatively. That could be another 5 to 10 years before regulations are written on this, and in the meantime, in my opinion, real damage could be done.

A third possible option is to try and amend the definition so that it fits this conjoined approach to stereo core biopsy. So let me open it up to the floor and any discussion on this.

Daniel?

DR. KOPANS: I don't know. It just seems very stra nge to me that FDA is supposed to be regulating mammography and quality. Imaging in mammography-guided procedures require the ability to perform mammography and to interpret mammograms. So, clearly, there are politics involved in this.

The hardest part of doing core biopsy is aiming at the right place, aiming at the right lesions and interpreting the lesion properly. Pulling the trigger on a spring-loaded needle is not something that requires a great deal of expertise, and needle localization, for that matter, should also be included. It is a mammographically guided procedure. It requires high-quality imaging. It requires quality control of the equipment. It requires training and interpretive skills. I think it should come under MQSA.

DR. D'ORSI: Ruth?

MS. McBURNEY: I think we need to ask FDA what is doable. To add this in at this point would probably open it up to a whole area that was not proposed. Is that right?

MR. SHOWALTER: It is very likely, simply, not possible to amend the definition to include what is suggested here without a re-proposal.

DR. KOPANS: Is this not a mammographic device?

MR. SHOWALTER: It is a mammographic device. There was an amendment to the interim regulations published on September 30, 1994 that exempted them from coverage under MQSA until appropriate regulations can be developed.

Since we did not propose to bring them back into coverage with this proposal, it is the opinion of counsel that we cannot do that without a proposal. That is not to say it can't be done. I am saying it can't be done without a proposal.

DR. KOPANS: A proposal from whom?

MR. SHOWALTER: A proposal in the Federal Register like we have here in front of us that we are talking about that proposes to amend the definition in the way to require it to be a qualified interpreting physician who does stereotactic core biopsies.

DR. KOPANS: Can I ask a question? I apologize if you have gone through this before. I have forgotten the term you used. When it was deferred, who decided that?

MR. SHOWALTER: That was a collective decision between FDA and the ACR where, after discussion, we found that there were no standards available at that time, and that it was deferred until appropriate standards could be developed. Is that fair, Pam?

MS. WILCOX-BUCHALLA: Yes.

DR. D'ORSI: Let me make a suggestion. Is it possible to add something like this following the definition if we look at that 900.2(s), radiography of the breast performed during invasive interventions for localization of biopsy procedures when an interpreting physician is directly involved in the intervention? In other words, add that statement in, and when that is the case, then it would not fall under the purview of an interpreting physician because they would be involved, anyway.

It sort of secured us, but it may be a way. I don't know if that is possible or not.

Pam.

MS. WILCOX-BUCHALLA: Pam Wilcox-Buchalla, ACR.

Charlie, maybe if you talk about what you think is the current time schedule since you are saying very clearly that you can't add it back in here without a re-proposal of everything, if you talk about where you are, maybe that would address some of the issues.

MR. SHOWALTER: Right. Well, as everybody knows, we did address this last fall at a meeting. We hope to have a proposal ready for discussion by the committee late spring, early summer of this year.

Dr. Finder is going to lead our development effort in that area. I have a new radiologist coming on board the 1st of

February who is going to be a prime staff person. I am still trying to bring on a physicist to help out, but we hope to have a proposal ready to go for discussion by the committee at the next meeting, very likely of this committee, which we expect now to be in late spring, early summer.

After that, we would have to do a proposal in the Federal Register. We would have to go through the same series of events that this proposal has gone through leading up to a final standard.

DR. KOPANS: You need quality control issues, but the interpretative requirements for interpreting mammograms, the requirements of a technologist, the requirements of the radiologist are the same. So it seems to me that even though you can't define the quality control measures for the equipment, you can define that it is a mammographic technique that requires people skilled in mammography.

DR. D'ORSI: Can I call on Larry? Larry has been involved with the discussion with the ACS and the ACR concerning this. How do you feel about this as far as deletion or inclusion? I know there are pluses and minuses on both sides.

DR. BASSETT: I think I would just be repeating what you have already said, and that is that we have discussed on a

couple of occasions -- well, one thing we have done is we have come to a consensus on some quality assurance and quality control issues that don't have anything to do with the personnel qualifications. So we have really got a document that will come out in the Cancer Journal for Clinicians that was written by a consortium of radiologists and surgeons who do this procedure. That will address things like some of the quality assurance activities, the selection of patients, and those kinds of things which I think was a big step forward.

Now, in terms of the personnel issues we have talked about, we met about that as well, and we have identified three ways in which this procedure is done. One is with a radiologist on their own -- not on their own, but basically in a radiology practice, a practice in which a radiologist and surgeon are working together, with the radiologist taking primary responsibility for those issues that are interpreting physician-oriented.

Then, there is a practice which we think is a minority where there are surgeons working alone who are doing this procedure alone, and I think our agreement at this point is that in that kind of practice, the surgeon should meet all the requirements of an interpreting physician since they don't have an interpreting physician taking responsibility

for those things that an interpreting physician has been defined to do in mammographic procedures.

So I would say that in the combined type of practice, one where there is both types of professionals working together, the surgeon in that kind of a situation should be required to meet certain requirements, such as how many needle biopsy procedures that they have done, that they maintain a certain level of those, that they do medical audit procedures in terms of the kinds of quality issues that involve doing that procedure.

So, in that kind of practice, the i nterpreting physician would take responsibility for the quality assurance activities involving the imaging. So there are really three kinds of models here that we are dealing with.

DR. D'ORSI: So maybe it is fair to say that, although at first glance, it might seem beneficial to exclude this, perhaps we should wait and hope that this combination consensus will be followed until regulations come in.

DR. KOPANS: All of our models that Larry has mentioned, somebody has to be a qualified interpreting physician.

DR. D'ORSI: Correct.

DR. KOPANS: It is a mammographic technique.

DR. D'ORSI: Correct, yes. That is true. That is true.

DR. KOPANS: So it may be that the surgeon pulls the trigger.

DR. D'ORSI: Right, correct.

DR. KOPANS: I have no problem with that, but the hardest part of this procedure going for the right lesion in the appropriate way.

DR. D'ORSI: That was the original intent of excluding the deletion, to make sure that someone was involved, but apparently --

DR. BASSETT: There is a very good program of quality control activities that Ed has been involved in as well that I think is very acceptable and very reasonable in terms of targeting and imaging quality control procedures and radiologists, tech qualifications and so on.

Do you want to speak on that, Ed?

DR. HENDRICK: What we have been working on is the QC document that would be the corresponding document to the ACR QC manual for mammography, but specifically for stereotactic, including digital image receptors.

Actually, we m ade very good progress on that. For the tests that are specific to stereotactic, we have drafts written of all of those. I predicted this spring, March or April. So I think we are on schedule for that.

DR. D'ORSI: So I guess you have the idea.

Yes. This is the last one, Dan.

DR. KOPANS: MQSA is designed to reduce harm, basically, increase the detection of, really, cancer. It is bad enough to miss a cancer on a mammogram, but to have found the cancer and miss it because you didn't target the right area, to me, is even a greater tragedy.

I understand the turf issues. I think that that is unfortunate that politics is getting in the way of quality care. I am disappointed, quite frankly, that that hasn't been addressed more forcefully by FDA.

DR. D'ORSI: I think we all agree with that. I agree 100 percent with you, Dan. This may be the best compromise vis-a-vis not getting inundated with a request to train nonradiologists.

All right. The next issue deals with the definition of a mammogram regarding the inclusion of the screening diagnostic separation. This was another issue that received a fair amount of attention, 29 letters. Almost all of them requested that the --

MS. SMITH: I have a comment.

DR. D'ORSI: Oh, I'm sorry. Yes. You have to yell because I am not looking back there.

MS. SMITH: Pat Smith from the Mammography Association of Maryland.

This turf battle that is going on, I know in Maryland right now, there are three facilities that the surgeons have set up themselves to do core biopsies, and I am involved in the middle of a turf battle between the radiologists and the surgeons at our facilities. The surgeons have said if the radiologists don't help them, which they don't want to do, they are going to open their own facility and take all of, quote/unquote, "our needle localizations away."

So the surgeons are the ones that are going to be doing these alone, and I think that needs to be addressed.

DR. D'ORSI: I know what you are saying. I agree. I don't know what else to do. You can't delete it, and then we will have the qualifications.

I would have pushed for that had not such progress been made between the two colleges. Anyway, I am disappointed, too. I really am. I think that this is an issue that could really in the interm, before regulations or before standards come out, could really be an area that is ripe for disaster.

Anyway, screening and diagnostic. Most of the letters, if not all, wanted the separation in and would like a definition of each one.

One of the let ters correctly stated that the regulations allude to diagnostic studies with magnification, et cetera, and if that is not defined, one or the other should be

changed, either take it out of the regulation that alludes to diagnostic mammograms or include the definitions.

Other letters said that the definitions should be kept for audit purposes. Several letters were worried about the lack of definitions causing confusion with the public not knowing the difference between screening and diagnostic mammograms.

Let me open it up for comments.

[No response.]

DR. D'ORSI: No comments? Then maybe we should consider putting that definition back in. Is that the consensus?

MS. KAUFMAN: No.

DR. D'ORSI: No?

MS. KAUFMAN: I think there was a specific reason, and I don't remember what it was.

DR. D'ORSI: The reason was that mammography should be good whether it is screening or diagnostic.

MS. KAUFMAN: Whether it is screening or diagnostic.

DR. D'ORSI: That is not a really solid argument. I don't see the problem in putting back the definition of screening and diagnostic. You are not saying one is worse than the other.

Yes.

DR. PATTERSON: You are going to have to define screening, and you are going to have to define diagnostic. I think everybody has a little difference in this aspect.

DR. D'ORSI: If the letters are correct, then you should amend those portions of the document which refer to diagnostic mammograms, and if you want to do that, that is fine, the.

DR. PATTERSON: Yes.

DR. D'ORSI: We are go ing to amend the things that allude to diagnostic and screening and leave the definition out is what I am hearing. Is that right?

DR. PATTERSON: Basically, that is editing by the FDA.

DR. D'ORSI: Right.

[Overhead.]

DR. D'ORSI: Adverse event, which is 900.2(c), I think we touched upon this before. Thirty days was too long to send out a report. There were two letters on that issue. Another letter required the definition of what is poor image quality. If you look at adverse event, it is an undesirable -- yes.

DR. KOPANS: We wanted to revisit the screening and diagnostic.

DR. D'ORSI: Okay, back to screening and diagnostic. Yes, go ahead.

DR. MONSEES: Well, yesterday -- we have only been here two days, haven't we? Yesterday, we were talking about follow-up procedures and communication with the patients, and I brought up that I thought maybe it was a good idea to separate screening and diagnostic for that purpose. We settled that with direct communication or some term like that.

Another thing that seems to be lacking in here, we almost saw a regulation that said that a radiologist should be on site for an implant patient, but what is lacking in here is something that says a radiologist should be on site for a diagnostic patient, and I think that is a whole other debate. I don't know whether or not that has been discussed previously, but if we are going to talk about that, and I do have certain feelings about that, we do certainly need to define it.

Has it been discussed whether a radiologist needs to be on site for diagnostic?

DR. D'ORSI: I don't think that separation has been made in the whole document, screening/diagnostic. Has it?

DR. HENDRICK: We used the term "diagnostic" this morning referring to magnification systems should be present if diagnostic procedures are done.

DR. D'ORSI: I think if you are going to have to amend the entire document, it is easier to put this definition in. If there are many spots that have screening and diagnostic and these issues aren't addressed, I don't see the big deal about including that definition. It is not a difficult definition.

DR. KOPANS: Carl?

DR. D'ORSI: Yes.

DR. KOPANS: And to define it, screening versus diagnostic, you can leave it a little. I mean, I think maybe the concern would be that if we say a screening mammogram is one that is done in an asymptomatic, otherwise, healthy individual who has no signs or symptoms of breast cancer, the ACR has definitions if you need them, but I think you need those definitions because there is going to be confusion as to whether I need the magnification tray or don't, and it is what we do all the time. There is screening and diagnostic mammography. I think it should be acknowledged at least with a definition.

Marsha?

MS. OAKLEY: It has been discussed, and I have been here 3 years. So I am not sure in which of the years, but it seems like 3 years today. I know that it was discussed, and we also got into whether meeting a physician for a diagnostic

should be present meant in the mammography unit, in the radiology department. It was like where should he be. I mean, in the hospital. So I know that we have discussed that, and that was one of the things that made it very difficult to define what it meant to have an interpreting physician for a diagnostic mammogram, just what we talked about earlier, what Larry and I were talking about. Somebody thinks screening is one think. Someone thinks screening is another thing. So I think it is a whole can of worms, and that is why we elected to go just with mammography.

DR. MONSEES: Dr. Bassett and Dr. Dorsey have been here for 3 years. I would like to know whether you think that we should put in these regulations that a radiologist should be on site during a diagnostic mammogram.

DR. D'ORSI: I agree with that.

DR. KOPANS: On site doesn't have to be minutely defined to be in the room watching the study being done. It can even be in the department, but I think that there are differences in the way screening is done and the way diagnosis is done, and that should be acknowledge somewhere.

DR. D'ORSI: Yes, Cass.

MS. KAUFMAN: Perhaps one of the Charlies can address us, but I don't think we can add that now without going back for

comment on that, correct? Because that is entirely a new requirement.

MR. SHOWALTER: Well, the issue of whether you can add something or not revolves around whether you are taking anything away from anyone, and the example, to go back to stereotactic, would be you are taking away the right to practice from individuals who are currently practicing without notice; that is, you haven't proposed to do that and now you are just doing it in the final regulation.

Here, it is not so clear whether you are taking anything away from anybody or not, and the one place where I see that you might be is if you define diagnostic in such a way that a qualified interpreting physician has to be somewhere in the vicinity, however that is defined.

You may be imposing a requirement without notice in that case, but that is a closer call and we would have to talk to counsel about it.

MS. KAUFMAN: That would be a particular problem for mobile companies.

MR. SHOWALTER: Yes, absolutely.

DR. D'ORSI: Yes, Rita.

MS. HEINLEIN: For those of us on this committee that were also together at the ACPAR panel, if you will remember, the amount of discussion that we had in defining diagnostic

versus screening and, more importantly, making the decision to state whether a physician should be on site for a diagnostic mammogram -- because one of the examples that was brought up from one of the radiologists there was that if she recalls a patient for a spot compression that she just tells the technologist, circles an area and says I want a spot compression. Now, that would turn that into a diagnostic mammogram. It would mean that she would have to be on site. She said that she is often not on site because she has highly skilled technologists. They know how to do the spot compression, and that is that. However, if we required a physician on site for a diagnostic mammogram, it means she would have to be there.

For all of us that were present at the APCAR discussion, I just remind you of that.

DR. KOPANS: There is actually a way around that. The wy around it is to define screening versus diagnosis based on signs and symptoms. You don't even have to say, necessarily, that a radiologist has to be on site for a diagnostic mammogram. We may agree that he or she should, but a diagnostic mammogram is a study in either a symptomatic individual or an individual who is referred on the basis of an abnormal screening mammogram. That really is the diagnostic mammogram.

How you perform it, whether you are in the same room, the next room, the other department or across town, we could debate about, but I think you should make those separations. A screening mammogram is a mammogram in an individual who has no sign or symptom of breast cancer.

DR. HENDRICK: Let me just ask this question. If what I am hearing is we should put in the definition, but then have no requirements for it?

DR. KOPANS: You are saying that if you are doing diagnostic mammography, you need to have a mag tray. You are having requirements based on it.

DR. HENDRICK: But there are other says to handle that one word that we have already discussed.

DR. D'ORSI: I think they have the sense here.

Let's go back to adverse event. We already went into the 30 days being too long to send a report.

MS. HEINLEIN: Let me flash back to school. Can we go to the principal and ask if they can't turn the heat up in this room? I mean, everyone is freezing.

DR. D'ORSI: Betty.

DR. PATTERSON: I just want to go back one quick second to the screening and diagnosis because, if I am not mistaken, the ACR in their terminology talking about it uses the

terminology of "a personal history of breast cancer." It was eliminated from that?

DR. D'ORSI: It is not.

DR. PATTERSON: It was in there at one time.

DR. D'ORSI: Not anymore.

DR. PATTERSON: It is gone, okay.

DR. D'ORSI: It is gone.

Can we go back? We spoke about 30 days being too long. Somebody wanted a definition of what poor image quality is. Any discussion on this? There are only two letters on here. We already discussed the first and what is poor image quality. That is possible to be defined, although it does say adverse events include, but are not limited to. So maybe that covers it.

Any questions or comments on this?

[No response.]

DR. D'ORSI: Okay, fine. Let's go on to the next one. One letter said that we should define contact hours, 50 minutes, like they do in academics. I think we should probably leave it as an hour, whether they get their 50 minutes or 55 minutes. Any comments?

[No response.]

DR. D'ORSI: No, okay. Double reading. There was confusion. There were four letters that came in on this.

What does double reading mean? We spoke a little bit about this before. Is it two physicians sitting down in front of a film collaborating and interpreting it, or is it two interpretations separated in time? So they want a clarification on this point.

Any comments? Do you want that clarification?

Larry.

DR. BASSETT: I think we should because, already, it has caused confusion when we were all discussing this earlier. I think double reading should be restricted to that process where you are having two interpreting physicians read the image to improve the sensitivity of the examination.

The other thing, independent reading is really just to increase the number of cases that you can read. It is not really involving the actual interpretation of the images.

DR. D'ORSI: So you are saying, then, independent reading is double reading?

DR. BASSETT: I think the term "double reading," at least in the literature, means that you are having two physicians interpret the same exam in order to reduce the number of false negatives that occurs. Isn't that right?

DR. KOPANS: And/or reduce the false-positives.

DR. BASSETT: Right.

DR. D'ORSI: Ruth.

MS. McBURNEY: I think you need to look at where we use it in the regulation in order to define it in terms of how we use it in the regulation.

DR. BASSETT: I think it should be changed in the regulation where it is used just to indicate that you can re-read the mammograms that have already been interpreted or review mammograms that have already been interpreted in order to maintain the number of cases that you have reviewed for purposes of meeting requirements.

We call that double reading, but I think in light of this confusion, we should change that terminology, not use double reading there.

DR. KOPANS: How about "double-image review"?

DR. BASSETT: I think just "independently review." You don't have to say interpret. How about "evaluate"?

DR. D'ORSI: Yes.

DR. KOPANS: I think what i am understanding you are saying, Larry, is that "double reading" has taken a specific definition elsewhere, and it is not to define what we are looking at here. I think that is a good point.

DR. BASSETT: Yes.

DR. KOPANS: It is like clustered microcalcifications.

DR. BASSETT: Right.

DR. KOPA NS: It really has a different connotation than a group of calcifications.

DR. BASSETT: Right.

DR. D'ORSI: Right.

DR. BASSETT: Except that in this case, I think it has confused people about what it meant. So I think it should be an independent evaluation of the two is really what you are doing here.

DR. D'ORSI: Okay.

DR. BASSETT: You are not really interpreting them twice.

DR. D'ORSI: All right. In an effort to reduce false-negatives.

DR. BASSETT: Right.

DR. D'ORSI: Okay. The next issue t hat received a fair amount of letters -- I'm sorry. Rita?

MS. HEINLEIN: You better keep looking in this direction, Carl.

DR. D'ORSI: I am going to look right there, now.

MS. HEINLEIN: So is the decision that you are just taking out the word "interpreting" and saying independently evaluating" I mean, that was the key issue there, just to take out the word "interpretation" and put in "independently evaluating"?

DR. D'ORSI: Well, the issue was they didn't know what it meant. So, if we can insert that and make it clear --

DR. KOPANS: Carl?

DR. D'ORSI: Yes.

DR. KOPANS: I thought what Larry was saying, and I would agree with him, is that we should do away with "double reading."

DR. D'ORSI: As a whole definition.

DR. KOPANS: Yes. The words "double reading" should be changed to something else because double reading has medical/legal consequences, the terminology.

DR. BASSETT: I think the FDA could come up with the right terminology for that. Don't you, Charles? I mean, you know what you are really doing there is having someone look at some images that have already been interpreted in order to meet their requirements for the number of images they have evaluated, and it is not "double reading" as it is used in the literature, and that is what has confused them.

DR. D'ORSI: I see, okay. So we should actually change that whole thing into some other term, "consultative reading" or whatever.

All right. The examinee issue, patient versus examine. This is one of the questions that the FDA has asked us to concentrate on.

In fact, most of the letters, 95 percent of the letters -- this is, by the way, 900.2(m), and this is utilizing the term "examinee." It means that any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

DR. BASSETT: Carl, we already discussed this earlier this morning --

DR. D'ORSI: We did?

DR. BASSETT: -- and determined that if we just clarified that in the definitions --

DR. D'ORSI: Fine.

DR. BASSETT: -- we could continue to use the term "examine."

DR. D'ORSI: Okay.

DR. BASSETT: So it wouldn't imply that women getting a mammogram by being called patients had something wrong with them.

DR. D'ORSI: Good, okay. That was basically for the self-referred.

Can we have the next sheet?

[Overhead.]

DR. D'ORSI: Facility. The letters here were interesting. They brought up the following question. If one entity just

interprets films and processes or produces mammograms in another location, but is owned by one person, are those two facilities? Does each one have to be?

The second letter on this really addressed a similar issue with multiple buildings on a campus with one ownership producing mammograms or reading in different areas or doing mammograms in different areas. Is that one facility or is it multiple facilities? I don't know. This is an FDA thing. I don't even know myself.

If you, for example, have the UCLA campus, maybe Larry has six buildings on his campus where he does mammograms at different addresses, but they are all on the campus, is that six fees or one fee?

DR. FINDER: Let me just say this. This has already been handled on the interim regulations.

DR. D'ORSI: Okay.

DR. FINDER: I mean, facilities are facilities, and there are 10,000 facilities out there already that we have dealt with.

DR. D'ORSI: Okay.

DR. FINDER: This is really not a big issue.

DR. D'ORSI: Okay. First allowable time, I think we also went into this. The people want a clarification as to what first allowable time meant. I think they were confused that

there were three boards that were recognized in this country for certification, and they probably start their process at different times. So I think we covered that already.

Lead interpreting physician. Only one letter that said change "lead" to "supervisor." I think we can kind of leave it like that.

By the way, just interrupt me, because I am going to keep on going, if you have any comments, okay?

Next.

Is there a comment ? Comment, Rita.

MS. HEINLEIN: I just want to ask a question about this first allowable time. I know we had a lot of discussion about that this afternoon, and we said we will get to that when we get to definitions. I feel like we get to definitions, and we say, well, we have already discussed that.

DR. D'ORSI: She caught on.

MS. HEINLEIN: We did. We did do that, didn't we? Okay, we said we will talk about it at definitions, and we got to definitions and we said no, we already talked about it.

DR. PATTERSON: Right.

MS. HEINLEIN: So the question is, is this definition of first allowable time accurate, and does it actually reflect the discussion that was held this afternoon?

DR. D'ORSI: I think it does. Let me read it. It means the earliest time a resident is eligible to take the diagnostic radiology board.

The thing that is confusing, it says from an FDA-approved certifying body. Now, does the FDA approve the ABR?

DR. PATTERSON: ABOR and the Canadian board.

DR. D'ORSI: Fine. So there a re three boards, then, that we are talking about, the ABR, ABOR, and the RC, whatever it is.

MS. HEINLEIN: So, to the radiologists that are sitting around here, everyone feels comfortable that this definition does, in fact, reflect the conversation that you all had this afternoon. Is that correct?

DR. D'ORSI: Yes.

DR. HENDRICK: I don't think so.

DR. D'ORSI: No?

DR. HENDRICK: Because questions were raised about a radiologist taking the boards and qualifying or not passing the mammography part, conditioning the mammography part. That delays passing, and that never really got clarified. There is also the issue that maybe they don't exactly get the first eligible time, but they get the next eligible time, but they get the next eligible time.

MS. HEINLEIN: Didn't he say something about within 2 years or something like that?

DR. HENDRICK: I would propose putting it within 1 year of finishing residency, and that got glossed over.

DR. D'ORSI: But the first allowable time indicates when you are allowed to take your boards. Then, the clock starts ticking there, and whether the ABOR does it in May and the ABR does it in June and the Canadian one does it in December, the clock starts ticking at that time. So the first allowable time really only reflects the initiation of the process. It doesn't really say anything about if you fail and how long does it take to do after that. That is discussed after, but it doesn't involve the definition of first allowable done.

MS. HEINLEIN: So, then, this definiti on does reflect what you wanted it to based on the conversation from this afternoon.

DR. D'ORSI: Yes. I think all they are saying is that there are three different boards, and they start at different times. Instead of saying everybody starts in June, they say the first time that each board says they are eligible to take the boards.

MS. HEINLEIN: Okay.

DR. KOPANS: Carl?

DR. D'ORSI: Yes.

DR. KOPANS: I mean, that seems all right to me.

DR. D'ORSI: Is that right, Ed?

DR. KOPANS: Is that all rig ht, Ed, in terms of what you are talking about?

DR. HENDRICK: I think it is going to be tough to inspect against.

DR. PATTERSON: The first allowable time?

DR. HENDRICK: Yes. I think you will have all sorts of red herrings and issues of interpretation here. It may be very clear to everyone in this room, but I think when you promulgate it among 20,000 interpreting physicians and 300 inspectors, you will have problems.

DR. PATTERSON: See, the only ones I could see where this would be a problem is if somebody had some reason, medical or what have you, that they took off from their residency and came back several months later, so that they didn't finish up in time to take the board when the rest of their class would take it. So it would be the following period of time to take the board. That is the only thing that I could see would be an interpretation of first allowable time.

I don't know. Maybe I am wrong.

MS. KAUFMAN: In the first place, there are not going to be very many people -- you are right, Elizabeth -- who come in under this. This is going to be a very small number.

In the second place, if you don't meet this, then you are not qualified to interpret mammograms, which is a level one deficiency, which always goes to FDA for final approval. So it doesn't really matter. You don't need to be that concerns about what an inspector might do because it is going to go to FDA for approval before they do anything.

DR. HENDRICK: Well, I don't agree that level one citations don't matter. I think they matter a lot.

MS. KAUFMAN: I am saying, though, that FDA approves them.

DR. HENDRICK: Well, whether they approve them or not, it is a big deal.

MS. KAUFMAN: Well, of course, it is. You are concerned about an inspector screwing up and making the wrong decision, and I am saying they don't make that decision on their own.

DR. HENDRICK: I am also concerned about radiologists who are proceeding in good faith and think they understand the regulations, not understanding them correctly, and causing problems like the level one citation.

DR. KOPANS: But I think there is a specific -- and I may be wrong about this -- there is a specific definition of board-

eligible. You have to have completed your radiology training program, and then you are board-eligible. I suspect you would become board-eligible.

I don't know. Carl, you do a lot of administration.

DR. D'ORSI: The board does not recognize board-eligible. You are either board-certified or not.

DR. KOPANS: When are you eligible to take the board s?

DR. D'ORSI: After 4 years of training.

DR. KOPANS: Yes. So that is when the clock starts ticking.

DR. D'ORSI: Right.

DR. KOPANS: When your 4 years of training is up, you are eligible to take the board. That is the way I would interpret that.

DR. D'ORSI: There are two parts to the board. There is the written and oral, obviously, and you can't go on to complete certification unless you pass one.

So, when you are eligible -- that is an interesting point. Actually, I just thought of this. Does the clock start ticking with the written board or does it start ticking with the oral board?

Betty.

DR. PATTERSON: This will add another bid of confusion because starting in -- what year is it? -- they are going to be taking the written at the end of their second year.

Starting next year. Then, they would be taking the oral at the normal time. It has to be after you complete. Complete your residency.

DR. D'ORSI: Well, as usual, Ed is right after I think about it. There could be a problem because of that year hiatus, and now you are saying a 2-year hiatus. Maybe you could handle that, right, the definition?

DR. PATTERSON: They will handle it.

DR. D'ORSI: Good.

MS. HEINLEIN: If we are having this hard of a time and we have discussed it for at least a half an hour --

DR. D'ORSI: Or 3 years.

MS. HEINLEIN: -- and we have also talked about these regulations for 3 years, can you imagine when somebody gets it on the street and they just start to look at it? I think it definitely needs to be looked at.

DR. D'ORSI: Okay. Somebody on the lead interpreting physician wanted to change "lead" to "supervising." I don't think that needs a comment.

Next.

[Overhead.]

DR. D'ORSI: Mammography unit. There is only one letter on this, and somebody said that they would like grid included in the definition of a mammography unit. It is probably

unnecessary because it doesn't specify everything in a mammography unit. It just gives an example. So I think that the definition is fine. Does everybody agree with that?

[Affirmative responses.]

DR. D'ORSI: Good.

Next, mean optical density, 900.2(w). Letters came in requesting clarification of the definition. I am going to have to defer to Ed and Joel here. People wanted the definition to include the average phantom thickness used and to change 6, whatever the hell that is, to a minimum of 3, to a maximum of 7. In other words, they wanted maximum and minimum instead of the average.

Yes, Rita.

MS. HEINLEIN: To the medical physicists on the committee, does it make that much of a difference to change it from 2 centimeters to 6 centimeters which is what it states now to make that change to 3 to 7?

DR. GRAY: I don't know what it is referring to because, if you are talking about does, it has to be a specified thickness, period.

MS. KAUFMAN: It is not. It is talking about mean optical density, and the only difference it makes is that in the past and under the interim regs, they primarily used

thicknesses of 2, 4, and 6. So I think that is what most physicists currently have, are those thicknesses. So that would be the only thing about changing it from 3 to 7.

MS. HEINLEIN: It is like saying what do you want, four quarters or a dollar.

MS. KAUFMAN: Yes.

DR. D'ORSI: Penny.

MS. BUTLER: This is the way it is currently described in the '94 ACR manual, and I see no reason to be inconsistent with that.

DR. D'ORSI: Okay. Next, modality. The letters received here wanted to expand the definition of modality to include digital, stereo, MR, breast ultrasound, nuclear medicine, CT. A lot of the letters written didn't realize that this is an X-ray technique.

Yes, Ed.

DR. HENDRICK: I think you can exclude the non-X-ray-based films --

DR. D'ORSI: Right.

DR. HENDRICK: -- and just include digital, and since stereo is excluded, you have to exclude that. So it would just be film screen, Xerox film screen and digital.

DR. D'ORSI: Yes.

Penny?

MS. BUTLER: Although CT is an X-ray procedure, I would also exclude that.

DR. D'ORSI: Right.

There was a fai r amount of the four letters that came in saying how could CME in Xerox be possible; in other words, how can we get CME with Xerox. That has to do with mammography.

People also wanted to exclude Xerox from the definition, but I think that is a moot point with what is going on. I think that takes care of that.

Any discussion on this? Rita.

MS. HEINLEIN: What is 42 USC 263(b)?

MR. SHOWALTER: A statute, MQSA.

MS. HEINLEIN: That is this statute.

So, really, all that modality means for the purpose o f this means the technology within the scope of -- is it screen-film and Xeroxography? Does it include digital? Does it include any of that?

MR. SHOWALTER: Modality means that you can read this. Modality means the technology within the scope of MQSA for radiography of the breast.

MS. HEINLEIN: Okay. And what is the technology within the scope of MQSA for radiography of the breast?

DR. D'ORSI: Xerox and --

MR. SHOWALTER: Well, I'd say right now, you have two. You have film screen and you have Xerox, and we certainly all anticipate digital in the not-too-distant future, full breast digital.

What we are concerned about, I will say, by naming them is the one that we haven't named that comes down the line next and causes us to have to do an amendment because it, indeed, was not named. That is why it was left a little bit vague.

MS. HEINLEIN: Nebulous, okay.

DR. D'ORSI: Betty.

DR. PATTERSON: I think the Xerox should be eliminated as an example there and just sort of leave it as a vague opening, film screen, possibly digital, and whatever else is on the horizon.

DR. D'ORSI: Mike.

DR. LINVER: Why doesn't it just say "the present modalities are" and list them? If we are going to say film screen --

MR. SHOWALTER: If we could name things, if you think it would be helpful and we could name things as examples without excluding future technologies that are within the scope of MQSA, then I think that is doable.

DR. LINVER: The reason I said that is because, by saying "example," it sounds like there are a whole lot more right now. By saying "present modalities are" and list them by

using the word "present," you imply that there may be future ones.

DR. D'ORSI: Rita.

MS. HEINLEIN: I think it is important to do that because we have had it come up in previous discussions throughout the day. When you talk about continuing education in the modality, we have already had people on this committee ask does that include ultrasound. So I think it would help. The terminology as it is used in the radiology community is modality means ultrasound, et cetera, et cetera. So I think it would be beneficial to do that.

DR. D'ORSI: You might put in here to stress radiography. I think that is where the confusion comes in. People are taking the other imaging modes.

Physical science. If Bob and Larry can move their heads a little bit.

DR. FINDER: Excuse me.

DR. D'ORSI: Yes, Charlie.

DR. FINDER: I may be mistaken at this late hour, but didn't we when we were talking about continuing education say that we would include things like MRI of the breast and ultrasound of the breast? If we used the term "modality" and define it here in this restrictive manner, have we gotten ourselves into a jam?

DR. D'ORSI: Yes, Dan.

DR. KOPANS: I was a strong proponent of including ultrasound and MRI for continuing medical education credits, but only with the assumption that, in fact, they always involve discussion of mammography. It is a little slop, but I think what we said was we didn't want to get into detailing the minutia of what a CME, a legitimate CME -- I am getting tired now. I can't think of the words. -- review would be included.

So it is not saying that MRI is the reality. It is saying that breast MRI, because it probably involves mammography, is a legitimate CME activity; of course, and breast MRI.

DR. D'ORSI: Ruth.

MS. McBURNEY: Yes. I think that where it talked about the individual modalities, it was a limited number of hours of CMEs versus the broad area of mammography for CMEs.

MR. SHOWALTER: You used a different term.

MS. McBURNEY: Right.

DR. LINVER: Use a term like "adjunctive imaging modality," "adjunctive imagine technology," something totally different for all of those other methods.

DR. D'ORSI: I don't think there will be a problem between the CME and this definition of modality.

Physical science. This was another question that the FDA wanted answered. The letters coming in stated that some of the categories were not broad enough, what about biological scientists, one of the letters stated.

Engineering, they felt should be limited to electrical or nuclear engineering; for example, a civil engineer wouldn't fit into this.

MS. SCIAMMARELLA: No, but you have in engineering, optical and mechanical engineering. You don't want to exclude.

DR. D'ORSI: Right.

MS. SCIAMMARELLA: Maybe you can exclude a civil engineer, but not the other division.

DR. D'ORSI: This is what people wrote, not what I say.

MS. SCIAMMARELLA: I don't think we need to eliminate that.

DR. D'ORSI: Ruth?

MS. McBURNEY: In normal terminology, biology is not included as a physical science.

DR. D'ORSI: Okay. Penny?

MS. BUTLER: I don't think we need to be specific on the type of engineering that is included or not included. I think, basically, engineers take basic course work, and then they branch off. I think we should continue to exclude biological sciences.

DR. D'ORSI: I think the definition makes that clear that you are not looking for specific knowledge, just the ability to do some of the calculations.

Joel.

DR. GRAY: I was uncomfortable with chemistry being included, but in the actual use of this term, we specify that there is a certain number of hours of physics required. So I guess I can live with that, but I would not include biological sciences.

DR. D'ORSI: So the answer to the FDA on this seems to be no, you don't need anything else.

Next.

[Overhead.]

DR. D'ORSI: Serious adverse event. The letters received here would like some examples of what a serious adverse event is, although let me read what it says over here. If you look at serious adverse event, it means an adverse event that may significantly compromise clinical outcomes or an adverse event for which a facility fails to take appropriate corrective action in a timely manner. So maybe you want to put some examples in there just to clarify what that is.

Time cycle. People were confused with time cycle. The letters that I received, that were given to me, stated that

perhaps "development time" or "development emersion time" should be used instead of "time cycle" because they were unclear whether this was the whole process of developing or whether it was just in the developing tank. I think that is something you can clarify.

Traceability. Now, this was a good one. This is for calibration of measurement instruments, and one letter recommended the standard definition, and I put it down there. Their standard definition or at least what this letter felt was a standard definition was the assurance that an instrument is related to national standards for an unbroken chain of -- what is that? -- comparisons -- thank you -- starting with and established by the NIST, Gaithersburg, Maryland.

Now, I don't know. I will have to defer to the people on the -- yes. Penny, Joel, Ed, anybody?

DR. GRAY: First of all, I thought we changed it from annually to biannually, every 2 years. So that is a change that will have to be made.

MS. HEINLEIN: Did we change that in April?

MR. SHOWALTER: In the parlance of the committee, that has been changed numerous times up until now.

DR. GRAY: We will change it again, then.

DR. D'ORSI: Okay. So the definition, then, the way it stands is fine, and you are going to change it to 2 years. I think that is it. Yes. Thank you.

Yes?

DR. KOPANS: What was the decision on screening and diagnostic?

DR. D'ORSI: I forgot. That we were going to amend the rest of the document and not deal with it.

DR. KOPANS: You are going to put in definitions of screening and diagnostic?

MR. SHOWALTER: We are going to look at whether we think that is appropriate or whether it is appropriate to not use screening and diagnostic in the rest of the document. I can't say right now which is the right way to go.

DR. KOPANS: I am trying to find it, but there was a section where you differentiate the requirements for equipment, as I recall.

DR. D'ORSI: Yes.

DR. KOPANS: I can't fine it. That magnification was needed. Otherwise, you are going to have to require magnification for all machines if you don't separate screening from diagnostic.

MR. SHOWALTER: I think we are going to have to find a way to make that distinction without using the term "screening" or "diagnostic."

DR. KOPANS: What I was going to suggest, if you do decide to go with the definitions, the way to avoid your concern, although Barbara will be angry, would be to leave out the requirement that a radiologist be on site, although I think we would all agree that that is what it should be, but you would say you have to put that in for review before you can include it.

MR. SHOWALTER: I heard your definition, and I think that is a plausible way to go if we do decide to use the definitions of screening and diagnostic. If you base it on symptomatic and asymptomatic, it is not at all clear to me that you are taking anything away from anybody. So I think that is workable.

DR. KOPANS: Make signs or symptoms as opposed to symptomatic or asymptomatic.

MR. SHOWALTER: Well, the right words, yes.

DR. PATTERSON: Okay. We are now moving along to -- hey, we are not too bad. It is 4 o'clock according to my agenda, and we are looking at the accreditation body, consumer complaint mechanism, and this is page 14897 and 14882. Marsha.

Accreditation Body

Consumer Complaint Mechanism, Consumer Complaints

MS. OAKLEY: One thing that I found, if you are holding your proposed rules, I have got it folded so that I can see both. When we look at page 14882 and page 14897, literally, if you fold it the right way, they are almost across from each other. So that might make it easier.

You can go ahead and go to the next overhead.

[Overhead.]

MS. OAKLEY: What I found is I was -- I'll tell you what, hold up on that for just one second.

What I found as I was going through the stack of letters that arrived at my house, and I didn't have 46 pounds to read, but I thought I had a lot, most of the letters that I received lumped consumer complaint together. They all pretty much came in together.

So, as I was going through the letters and looking at them and trying to pull things out, unless the person had specifically given me the number, you didn't know whether it went to one or the other, and that is why I said if you open it up this way, you can see that they are almost alike as you come down. So many of the comments that people wrote about, I don't know which one they wanted to put them under. They just put it under a basic consumer complaint.

The other thing that I wanted to say was that, as I read through these, the majority were from facilities. I could only clearly figure out that there were two that I consider to be from consumers. So, again, while we might have hoped that consumers would comment on this, it was very clear that they were coming from the facilities.

The other thing -- and I just wanted to let you know for kind of an overview -- is big facilities, the American Cancer Society, the American College of Surgeons, the American Hospital Association, numbers of letters from radiologists, either from the physicians themselves or from the RTs, managers, office staff, but again, I could only pretty much identify two letters that were from consumers. I will just give you an overview here, and I think you will see as we go along, generally, most of the comments felt that this is not a needed section; that it is an overburdening. You are going to see that as we go along. What I am going to do first is I am going to put up the three questions that came from the Charlies that were the questions that they wanted to have addressed. So these are the three.

[Overhead.]

MS. OAKLEY: I am just going to have them up now, and then we will come back to them, but I thought maybe for the

purposes of doing this, it might be to look at it initially, if you haven't already, and try to develop regulations that are essential for quality, require the force of the law and are enforceable, does the following regulation meet the requirement, provide the consumer with adequate directions for filing a complaint with the facility's accreditation body. If the facility is unable to resolve a serious complaint to the consumer's satisfaction, the goal of the consumer complaint mechanism is to enable patients to file complaints.

Should FDA prescribe methods such as having requirements for written instruction or other such mechanisms? Should all patients receive information to enable them to file a complaint?

We can go to the next one.

[Overhead.]

MS. OAKLEY: Carl, I am going to go through this real quick. You help me out here.

I went ahead and put up the definitions because, again, as we go through the comments, repeatedly, you are going to have comments that are going to say what is an adverse event. So Carl read it off and we have already been through that. So you can go ahead and go to the next one.

Again, a serious adverse event, and if you push it up a little bit further, the other thing on the bottom you are going to see is a serious complaint, and again, that will come up in the comments.

Okay, go on to the next one. At this rate, we will get out of here.

[Overhead.]

MS. OAK LEY: What I decided to do was just really kind of pull out some of the comments. So these are some of the direct comments. Adverse and serious adverse events have negative connotation, and again, that came up, if you want to just kind of slide that up a little bit for me -- I'm sorry. Do you have a name, sir?

STEFAN: My name is Stefan.

MS. OAKLEY: What is it?

STEFAN: Stefan.

MS. OAKLEY: Stefan has been sitting in front of me. I didn't even know his name.

Stefan, if you will just push it up jus t a little bit. You will see, again, as we continue to go through these that more and more people would say that they thought the wording automatically had a negative connotation, and there was some concern as to whether that implied that there was supposed to be a problem, and whether or not this was something that

was really a health and safety issue or was it an issue that was a violating of a proposed regulation.

Here is another one. The word "complaint, a negative connotation. So, again, another one.

The suggestion on this one was that perhaps we retitle it a consumer feedback mechanism or a consumer comment mechanism, and I thought that that comment somewhere in the past 3 years, I had heard that repeated before.

Cass?

MS. KAUFMAN: I just wanted to point out that in the enacting legislation, it specifically uses the word "consumer complaints."

MS. OAKLEY: Okay.

MS. KAUFMAN: So, when we hear those kind of comments, I am not saying that we have to do that, but I think we need to keep in mind where this is originating from.

MS. OAKLEY: Right.

MS. KAUFMAN: It says that this advisory committee will make recommendations and assist in the establishment of a mechanism to investigate consumer complaints.

MS. OAKLEY: I think some of the things that you will find, or at least I found, was that a lot of people's comments, they had not looked at the definition section. It was very clear to me that they had never -- you know, they were

asking what this means, and they had not ever looked at the definition section.

So, again, in going through the comments, I think it is a matter of just some clarity, perhaps making it simpler or making them realize that the things that they had complaints or concerns about are there. It is just an oversized document that they did not look at. They just went into one area.

Again, "unresolved" and "serious" are not adequately defined, and again, why put the definitions up?

They wanted to know if accrediting bodies have to assemble boards or committees to hear these complaints, will there be an appeal mechanism. So, Charlie, I don't think you want to do that.

MS. KAUFMAN: Well, there is an appeal mechanism.

MS. OAKLEY: Right, and we know that.

[Overhead.]

MS. OAKLEY: Concerns, again, that they are not well defined, that consumers will not understand. Now, again, keep in mind, except for two comments, there were all from facilities, larger organizations. So, continually, I heard consumers will not understand, consumers are confused. I don't know that they -- in a lot of respect, the consumers got much credit for some things at all.

Consumers will not understand what is meant by this, and again, I think that is where education has to come in.

I would further request clarification regarding the consumer complaint. I believe what the FDA is considers as a serious complaint should be listed, and it is if you take the time to go back and look.

I'm sorry?

DR. KOPANS: You keep referring to adverse event. Where are we finding this in the document?

MS. OAKLEY: Okay.

DR. KOPANS: Besides the definition.

MS. OAKLEY: In Carl's section on definitions.

DR. KOPANS: I understand the definition, but where is it in the consumer complaint? Maybe it is the late hour. The consumer complaint mechanism and then serious adverse events, where is the connection? I am missing that.

MS. OAKLEY: What I am looking at, what I have is the complaint mechanism. You don't see it listed there at all. If you go down either one of them, at least what I have in mind, as you are looking through it, it is not -- go ahead.

MS. SCIAMMARELLA: I think we never define. That was an issue that -- a serious adverse issue that people cannot communicate. I mean, one of the issues here was language.

MS. OAKLEY: Flip it up, just a little bit here.

MS. SCIAMMARELLA: I don't think you can --

MS. OAKLEY: Here on the bottom --

MS. SCIAMMARELLA: Yes.

MS. OAKLEY: -- one person said what constitutes a serious complaint, is it a false-negative, is it an error in interpretation, is it an unhappy examinee bent on vengeance. I don't think we ever really clearly defined that.

MS. SCIAMMARELLA: Never define what it is.

MS. OAKLEY: Am I wrong on that, Rita? I don't think it was very clearly defined anywhere.

Yet, if you are looking throughout the document and you see where here is an adverse event or here is a serious complaint, they are not sure what it is supposed to be. There was one comment that came through, and we heard again today, too, about the room is cold or you didn't like the carpet or something that is just really not something that you would consider to be a complaint.

So, again, the definition is something that I think we need to really define for them.

Am I losing you?

DR. HENDRICK: Yes.

MS. OAKLEY: Okay.

DR. HENDRICK: I mean, serious complaint is defined on page 14869, and it is defined in terms of report of a serious adverse event.

MS. OAKLEY: Right.

DR. HENDRICK: Serious adverse event is defined on the same page.

MS. OAKLEY: Right, but I don't think they put the two together, Ed. I don't think they looked at it and put it together.

DR. HENDRICK: Well, yes. I mean, there are a lot of things that people who commented on didn't get right, but do we need to waste our time discussing that?

MS. SCIAMMARELLA: I think if the issue is the location to the consumer, that what you are expecting to complain -- if we don't explain -- for what are coming from. Women go for a screening, and they don't explain what is a mammography. What has happened? The tech and the nurse do not have time to explain to the consumer. So then how are you expecting somebody to complain when they don't know where they are supposed to complain? I think we do not give enough time to dealing with the consumer issue.

[Overhead.]

MS. OAKLEY: I think what I felt as we were going through was that it is in the document. There are the definitions

of what these are, but yet, if the definitions are in there, why are there so many comments where people are saying what is it, what does it mean, be more specific.

Here is the one, "compression hurts," "the room is too cold." So it is there, but I guess what I am saying are here are all these comments that have come that have said what is it, define it, make it so everybody understands it. It's an education thing. These, again, are all from basically providers and large institutions. If you are talking about a consumer complaint mechanism, first of all, how do you convey that to the patient? But then, the other thing is, where is it listed so that this patient knows what these terms are? Every patient is not going to pick up the Federal Register or the rules. So what does the patient know, and what are we giving to her? I think what you are going to find that I found is that they do not know what it is, and they don't really know from what we have so far how to access it back to the appropriate people.

DR. KOPANS: I am still confused about this. A complaint is a complaint. You may complain the room is too hot. You may complain the room is too cold. Are you asking there should be a definition of complaints?

MS. OAKLEY: I think we need to think about what definition is going to be handled at the local facility and what

definition of a complaint needs to then be forwarded to someone else.

In other words, I don't think that what these comments are saying is that all of these concerns are going to wind up at the FDA level. I think there are many of these that are not considered to be a serious or an adverse complaint, and they should be taken care of at a local level, but I think the consumer needs to know in some mechanism, if these are what they consider to be a serious complaint, an adverse complaint, where does she go with that.

Larry?

DR. BASSETT: I agree. At this point, now that you are going through this, it does need to be more specific for these facilities.

Dan, an example would be if you were going into a facility and had a mammogram and you became aware at that time you were having it done that the person taking it was the receptions or the secretary, wasn't qualified, trying to have the facility resolve that probably is not the most appropriate approach.

I think the FDA did want to have the things that could be resolved by the facility resolved at the facility level since they were most able to rectify or correct the problem, but there are some things that probably should go on to the

accrediting body which would then decide whether it could be resolved or passed on to the FDA.

There are some things, however, that may not be that obvious. They just don't get resolved, such as lost films and so on, that the patient may want to complain about as well, and they have to be allowed to have a mechanism to do that.

So I think what they really want is for the facility to have some kind of mechanism to inform patients that there is another level to raise a complaint to if it is a serious complaint.

DR. KOPANS: But if it says that here --

DR. BASSETT: I think the problem is these facilities want better definition.

DR. KOPANS: They want it so that the patients don't go to the FDA with every little complaint.

MS. OAKLEY: Right.

DR. KOPANS: But there is nothing to stop the patient from going to the FDA with every little complaint, and I wouldn't want to stop her.

DR. BASSETT: Yes.

DR. SMITH: I just want to reinforce this line of presentation because what we are getting is, yet, another glimpse of the fact that the proposed final rules in some

areas were extremely confusing. In fact, some of the things I have been reviewing are a good marker of the lack of clarity on how many people misinterpreted what you are trying to get across.

MS. OAKLEY: Well, my reason for doing this first section was, as I said, I only had two out of the stack that is over there that I could identify as consumers. So these were agencies, facilities, and they were certainly confused, and that is what I was trying to show.

Elizabeth?

DR. PATTERSON: Yes, two comments. Number one, I think the whole document is not user friendly, and I think we all admit to that and that that is part of the reason, I think, that they were unclear on some of this.

If you turn to page 14863, which is part of explanations, I guess, that were done, they actually do give sort of examples in this part. It did not come in later when they are giving the definitions, and maybe the examples that are used on that page should be used in the definitions because I think that sort of helps on what is serious and what is adverse, or they talk about the room too cold or something like that.

MS. OAKLEY: But I think what we are showing here is that it didn't come together. So that is why these comments were such that they were.

Go ahead to the next one.

Roland, you had a comment.

DR. PATTERSON: Dan had one, also.

MR. FLETCHER: Well, my first comment was it didn't appear as though the concern was necessarily for the consumer. It seems as though some of these facilities need to be doing a job of education of their own.

You said that these comments came from the facilities. Th e facilities need to be always prepared to deal with comments like the room is too cold, not because of these regulations, but because patients do complain. I don't understand why we are trying to --

MS. OAKLEY: The one comment that is here, this entire section will confuse the patients -- I thought from what the comments were that came though, it wasn't the patient that was confused. It was the other people who were confused.

MS. SCIAMMARELLA: I think we faced this in Chicago with a lot of complaints that the tech doesn't communicate because there is a language barrier with different ethnic groups. They don't send an explanation that they need to come back for another X-ray because they send it in English and they

don't send it in an appropriate language. So there are more serious situations, and the person gets scared. They don't know what to do. It is not appropriate communication with the patient. I think that is one of the big issues, too.

MS. OAKLEY: There were 23 comments that said this is going to confuse the patient. Again, these were facilities who said 23 different times the patients will be confused.

Ruth?

MS. McBURNEY: I think that we need to leave the regulation rather broad, but I do think there is going to need to be a big education process both of the facilities in preparing their system for resolving consumer complaints. I think it would be a good idea for FDA to work out a guidance document, along with, maybe, the accrediting bodies or something.

That is usually the method that is used when a rule is rather broad and is open to a lot of interpretation.

I don't think that you can get real detailed in this, but I do think they are going to need a lot of guidance and help.

MS. OAKLEY: I think one of the things that was, again, apparent from some of the comments -- these were little bits of the comments -- one of the things that it talked about was the certificate, that a patient came in, and within the certificate, there is written the contact back to the FDA.

Many times, those certificates are hanging on a wall, not necessarily at eye-level height and not necessarily where she is even going to sit down to fill out her paperwork or have her exam done.

So no one is saying when she comes in for an exam this is what you do if you have a complaint, and you are also not always going to hand out as you are talking with this patient, if this is a problem, this is how you get a hold of us. No one wants to think you are going to have a problem. One of the suggestions was that the p atient be given an evaluation form which would then allow them to say good things and perhaps bad things as well, and it was given to every patient. So that, it wasn't, then, just looking for the patient who had a problem.

DR. KOPANS: I am getting very confused by all this because it seems to me that the responses that you got from facilities were responses that were saying we don't want FDA to get these complaints about us, particularly the minor complaints. It is too nebulous. It is not clear. That, to me, is irrelevant. If a patient needs to complain, she needs to complain.

The business of, I think, going to a patient when you are bringing her into your facility and saying remember you can complain by doing X, Y, and Z is the wrong way to start off

a procedure, but at the same time, you have a patient who says I want to complain, how do I do it, you have, well, here is how you do it.

I am getting very confused with this need to define what the complaints are and all that. I think this actually spells it out very clearly, and if a facility maybe wants to know what is going to be a legitimate way of doing this, it is left open so that you can decide. You have a mechanism. You are showing you have a mechanism, and spelling it out any further, I think is a major mistake.

MS. OAKLEY: What I am saying is this came in with litigation concerns. I mean, again, here we are talking about consumer complaints. Again, most of the comments were from the facilities, and there were four comments that were pretty much related to something that had litigation.

In the judicial system, it is public. What if this regulation is public, and our sensationalistic news media, it could lead to unfair accusations? The issue of collecting and resolving serious consumer complaints is a good idea, but be cautious. We are concerned about false accusations. What are we trying to accomplish with this regulation? Explain the number of medical/legal litigations that occur on a daily basis within the United States.

To me, it sounds as if the facilities are really frightened. They are really frightened that all of these consumers are going to send in things directly to the FDA.

I go back to saying I think we need to really educate the consumers, and we need to work with the facilities to let them know that the FDA is not out to be the bad guy; that if there is a real problem, we would still prefer it, try to go to the patients and the facility.

Charlie?

MR. SHOWALTER: Let me just respond to a little bit of that. I completely agree with that. I think there is a major education campaign that needs to be done.

I think anybody who expects the consumers to read and understand the Federal Register is dreaming. Even facilities, largely, will not read and understand exactly the implications of what all is in the Federal Register.

So our initial education campaign, after this gets finalized, needs to be to prepare something very clear and understandable to all facilities, hopefully, in conjunction with all of the accreditation bodies. That would be the ideal way to do it to me, explaining what their responsibilities are and that we expect most situations to be resolved locally. When they can't resolve something locally, they can get their name and address of their

accreditation body from their facility, and they don't need to know anything beyond that because that is the next step is to go to the accreditation body.

MS. OAKLEY: And I don't disagree with you.

MR. SHOWALTER: So I think the fact that some people who read this are confused is perhaps not surprising, and I think that it is incumbent upon us to develop clear information.

MS. OAKLEY: And I think, again, it goes back to they feel like, you know, Big Brother, the FDA, is looking down upon them, and I think you are right. People are not going to read the entire Federal Register. I certainly didn't expect to do that, but again, I am just a little amazed that of all the comments and that these were only two consumers in here, this is what you are seeing.

Cass?

MS. KAUFMAN: I know in April, we had a lot of discussion about this, and I think that we decided that we did need to have some kind of a guidance document for those two definitions, serious and adverse and that kind of stuff, where we would give some examples in that kind of thing.

MR. SHOWALTER: I would expect that to be a part of any education materials that we develop.

MS. OAKLEY: I did check with Charlie to see if there were any major changes, and there really weren't. So what is here is pretty much the same.

MS. KAUFMAN: No, I am talking about the guidance document.

MS. OAKLEY: Right, guidance.

[Overhead.]

MS. OAKLEY: This was the one I loved. My first response to consumer complaint mechanism is "oh, no, more paperwork." It was talking about establishing a document, a consumer complaint mechanism, is unnecessary, cost unjustified, paperwork unjustified. Why should mammography be picked on when no other medical service is required to have such a mechanism in place?

The consumer complaint mechanism is a real burden to both the accrediting body and the facility. There is no doubt in my mind that those were all responses from facilities.

Dan, again, go ahead.

DR. KOPANS: Again, I think that the facility should ask themselves when a consumer complains, what do you do. Hang up? No. You give your supervisor the phone. I mean, everyone has a mechanism for this.

I think the only thing I could see where they would be concerned about the medical/legal consequences is maintaining a file with all of these complaints. So someone

could theoretically raid the file and say I have got 100 complaints from this facility, even though they may be doing 100,000 mammograms or something.

MS. OAKLEY: I was asked to review the comments.

Rita?

DR. KOPANS: I wouldn't make any changes in this. I think the wording is very good.

MS. HEINLEIN: In fact, I was going to say the same. I mean, I guess the question becomes -- Marsha, do you or does anyone else on the committee have any comments to the FDA as far as the possibility of making any changes, or do we just say this looks good the way it is? I mean, I think it looks good the way it is.

MS. SCIAMMARELLA: I think we are going back to the same thing that has been said here, that we cannot regulate certain things. We are back to the same point.

I think if there are serious issues on how we educate a consumer, there are institutions who have consumers on their boards, community clinics. There are mechanisms who act voluntary to educate the consumer. I mean, it is the intention to do something, to educate the consumer. I have no sympathy for this kind of complaint. I don't know who can be in that position and suffer lack of communication

with a patient about need and service and be scared that you don't know.

It could be the same thing if your child has some problem and nobody can communicate it. I think there needs to be a piece of education to the consumer and maybe a survey, like any kind of protocol that could be a kind of mechanism that the consumer going has consumer satisfaction, protocol to see what are the complaints or what are the people's basic questions. It could be simple things without a complicated system.

MS. OAKLEY: One of the things, it talks about adequate directions here, and that was one of the questions that came up. Again, if you are not going to go up and put your nose on top of the FDA certificate, you need to be handed something. You need to have something that provides the information.

The other thing was a serious complaint could be handled by the ACR peer review. Pam, is there such?

MS. WILCOX-BUCHALLA: Pam Wilcox-Buchalla.

We have a consumer complaint process under the interim regulations. We get complaints on average of about three or four a month from a variety of facilities all over the country. The process is in place. Facilities just need some education. I think that is it.

MS. OAKLEY: Okay, so you have that.

Go ahead.

MS. SCIAMMARELLA: We need to establish something like that, that could be some part of the information.

MS. OAKLEY: I think what Charlie is saying is that a lot of this can go into the guidance.

MS. SCIAMMARELLA: Okay.

MS. OAKLEY: There is every ability that you are going to have that.

This comment came up, and I thought it was interesting. All you have to do is drop down to the bottom line. It talks about we do this, we work with our patients, and it talks about JCAHO. Well, that is hospitals, and we all know that there are many, many other facilities that aren't a hospital base.

So, yes, if you are a hospital, you will have all of these things in place, but if you are a freestanding facility, that doesn't necessarily mean you will.

Flip it on around.

I think for the majority, it does, and I think for that to come, you obviously knew that was coming from a hospital.

[Overhead.]

MS. OAKLEY: Complaints handled on an individual basis, again, goes to a guidance document. I think, basically,

what we are saying here is that adverse events -- here is one. Adverse event should include failure to send a mammography report in a timely fashion. Thirty days is too long. Is that an adverse event?

Question, the wisdom of the facility to prescreen complaints and determine which complaint is serious. I found this interesting because, essentially, you are telling a woman who has got a complaint, she is going to complain to the facility, and then how does she know that gets handled appropriately? Is there some type of response? Does it get handled? Does it get dropped? Does it get, essentially, kind of put under the carpet? So that comment went on in a further paragraph.

We believe facilities should be required to record all complaints and provide consumers with directions for filing complaints. Again, it goes back to who gets it, and it is pretty well described in here that there should be a reporting mechanism back to the FDA, but this is, again, where people were saying it is more paperwork, we are already doing this, and why do we need to do it.

One more.

[Overhead.]

MS. OAKLEY: Flexibility. Many people talked about they needed to have flexibility. There ought to be a policy in

place in their procedure manuals and to have some kind of flexibility.

We applaud the inclusion of a mechanism for handling consumer complaints. Can you guess that that was from a consumer?

The American Hospital Association supports, but again, does the consumer complaint process need to be provided to each examinee/consumer or only those that have a complaint? Again, I go back to the one letter that was pretty lengthy about if there is something that is more positive, that there a response kind of an evaluation for everyone, that maybe they can drop off as they leave the facility. Then, if there is a problem, it is not like you have handed her a form and she is going to fill it out. What is she going to do with it?

I have actually been in facilities where, before you leave, in front of somebody at the front desk, you are being handed a form and asked to evaluate them. I don't think that most people would feel comfortable enough to give a negative evaluation with someone sitting right there looking at them.

MS. HEINLEIN: I don't think it was the intent that each examinee/consumer would be provided with the consumer complaint mechanism. I think it is just intended that they have something on file within their facility so that they

know what policy to follow if someone does come to them with a complaint.

MS. OAKLEY: I don't think it was either. That was a suggestion.

Joel?

DR. GRAY: I think we have missed the boat on this. I have my Marriott key card in front of me, and it doesn't say a bloody thing on here about complaints. It says on the bottom, "Comments, concerns or questions, please dial Guest Relations." This word "complaint" is very inflammatory. Could this be changed to "consumer comments" or something less inflammatory?

MS. OAKLEY: That was a concern.

Dan?

DR. KOPANS: The last one, does the consumer complaint mechanism process need to be provided to each examinee/consumer or all of these others, it says right here unresolved -- I'm sorry. If the facility is unable to resolve a serious complaint, then they have to provide the consumer with adequate directions for filing. I don't know how much clearer you can make that.

MS. OAKLEY: Somebody's comment.

DR. KOPANS: Well, they ought to be able to read.

MS. KAUFMAN: The bottom line is it is up to the facility to establish their own system. If their system wants to include a notification to every patient, that is fine. They can do that. If they don't want to include that, that is fine, too. It is pretty much going to be up to the facility and the accrediting body to approve whatever mechanism they have.

All we are saying is they have to have some kind of a system, but we are not delineating what that system is, and I think that is probably the way that it should be. It is up to the facility to determine what works best for their patients and their consumers.

MS. OAKLEY: If you will go back, I think it is going to b e the second overhead that says consumer complaint mechanism with the questions that were posed.

[Overhead.]

MS. HEINLEIN: Marsha?

MS. OAKLEY: Yes.

MS. HEINLEIN: Just another comment on what Joel brought up. According to the enacting legislation, we have to have something in here concerning consumer complaint mechanism. Does that also, then, mean that that is the same verbiage that the facility needs to use? Could the facility, then,

just call it the consumer comment mechanism? I mean, how would it be inspected upon?

MR. SHOWALTER: Absolutely. I would fully expect us to elaborate on that in any communications to facilities that if they offer an opportunity for a consumer comment, that that is a successful implementation of this program. I think that is a very good point.

I do think the legislation, the complaint mechanism is unfortunately too negative, and that anything we can do to soften that will work towards better relations between consumers and facilities, and that is what we want.

DR. KOPANS: Excuse me.

MS. OAKLEY: Okay.

DR. KOPANS: I need a clarification, then. It seems to me that the concerns that people are expressing are what are we going to be cited for. In other words, is my mechanism where I say call the chief technologist and we keep a file of the complaints on record, is that sufficient, or is FDA going to come back to me?

I am a little concerned, Charlie, with what you just said that I have to have a stack of consumer comment sheets. I don't see that anywhere in what you have got in the regulation. That is why I think it is good. You are just establishing a system of documenting complaints, maintaining

a record of the complaints for 3 years. If you can't resolve the complaint, that consumer, not everyone who comes in the door, but that consumer whose complaint you can't resolve needs to know what the next step to take it, and you have to report unresolved serious complaints.

It seems very straightforward, but I think what people are concerned about is FDA is going to over-interpret this and say you have to provide every consumer.

MS. OAKLEY: I would just say that I chose to do it this way instead of summarizing. Most of the ones that have been before me, there has been a summary.

I chose to put up the actual statements because I was asked to do a summary, and these were statements that came from people who, quite frankly, I think, are afraid that Big Brother is coming after them.

MR. SHOWALTER: Well, indeed -- I didn't perhaps speak clearly because I don't think you took from what I said what I meant, and what I meant to say was that would be one mechanism. Apparently, that is a concern of people, is that an acceptable way to implement this. I would say yes, it is. It is certainly not the only acceptable way to do it, and I think that also has to be made clear.

If you want to tell everybody who comes in, here is where you comment, that is fine. If you don't want to do that and

you have some other way and you have a means of responding to individuals who do have something to say, that is fine, too. There are lots of ways to do this, and there is lots of facility flexibility, so long as you provide this avenue to get information back into the facility.

MS. OAKLEY: I have got the three questions up again. Elizabeth?

DR. PATTERSON: Yes. I don't think that the facilities are really concerned about FDA coming in and inspecting to see if this is the mechanism or if they have an acceptable mechanism.

I think what they are concerned about, at least the feeling that I got from your comments that were written there, were the fact that, number one, this is negative-sounding. So a consumer comes in and complaints and they are not happy about it, and the fact that they are keeping these records for 3 years, the consumer goes back out there and heads to the media, PrimeTime or whatever have you, and says they have whole stack of complaints, consumer complaints, I think that is what the facilities are concerned about, or that the third-party players or the HMOs and et cetera will hear they have got all of these consumer complaints; that they have been accumulating.

MS. OAKLEY: Again, it is a privacy issue.

MS. SCIAMMARELLA: I think you need a kind of mechanism, a card, whatever we want to call it, patient satisfaction. If we give it to all the patients, it can be very general, if the service is adequate, it is good, it is bad, and that is a way to have to ask for that kind of form. I don't think it will scare anybody, but at least it is a way to see if the people are satisfied with the service of that facility.

MS. OAKLEY: In the essence of time, let's go through these questions here.

[Overhead.]

MS. OAKLEY: I think the bottom one, we have already said -- Rita, you have pretty much addressed that, should all patients. I don't think it was the intent, perhaps, that all patients would have a negative complaint, but should all patients receive information to help them file a serious complaint or do you just wait until she complains and call back. Up to the facility.

Coming up from the bottom, the goal, should FDA prescribe methods such as having requirements for written instructions and other mechanisms? I think, again, we are talking about the facility.

So I think, basically, what we need to be able to do is, in a guidance document, maybe tone it down so it is not so negative, give them some things to follow, but basically, I

think that what I saw coming through was a lot of facilities. Again, two comments from consumers only.

DR. PATTERSON: Good.

Yes, Joel. Do you have a comment?

DR. GRAY: I would like to make one additional comment. We were talking earlier about how important feedback is between the radiologist and the technologist, and what we are really saying here is let's get feedback between the customer, the patient -- excuse me -- the examinee --

DR. PATTERSON: The examinee.

DR. GRAY: -- and the facility, and I think positive feedback is going to be just as valuable and more valuable than negative feedback, but I think here is a good opportunity to set up a good mechanism to do that.

DR. PATTERSON: But do you think that this should be legislated, feedback on everybody, or leave that up to the facilities?

DR. GRAY: I think it is unfortunate that the regulation says complaint mechanism to start with, and I think it should be suggested that there has to be a mechanism in place, but leave it up to the facility as to whether they want to make it a card to everybody or how they want to handle it.

DR. PATTERSON: All right. Moving right alo ng, we are now, believe it or not, down to the last. Mike, you are going to be doing alternative requirements, and that is on page 14883-4. It is 900.18.

Alternative Requirements

DR. LINVER: It is down at the bottom of the first column. I just got the 5-minute warning from Charlie. So this is going to be quick.

The alternative standards got a total of 11 comments, much to my relief. 4.7 ounces, I was very happy about that. There were three general comments. One agreed with the section. Another thought the section ought to be omitted because the implication was that it would create nonuniform standards which went against the original legislation. There was the potential for one person within FDA making a decision, at least that is the way this was interpreted by this one individual who complained.

There was one comment that agreed, but felt that any facility which was given an alternative approval should be monitored to assure that that alternative was as good as the "standard approach."

[Overhea d.]

DR. LINVER: There were some specific comments in (a), criteria for approval of alternative standards. The comment

was to reduce the justification to just "provide benefit to human health" rather than this list that exists as you see here.

Under (d), under ruling on applications, there was one comment that this should be deleted, to delete providing a summary to our committee because they felt that the committee had no authority to review, approve or reject any action on alternative standards.

There was another comment that felt that the committee should be included in determining guidelines for alternative standards.

Lastly, there were comments regarding (f), which is at the top of page 14884, the applicability of alternative standards. There were four comments that felt that the FDA should reserve the authority to extend the approval beyond the applicant and a separate comment that felt that if approval were granted, it should be approved for general use by everyone rather than requiring other interested parties to apply separately.

Now, this is the sum total of the comments. Is there any discussion on any of those?

I'm sorry. We better go back to the previous one or just the second stuff. Thank you.

Rita?

MS. HEINLEIN: Just one comment on the one that says ruling on applications. Delete providing the summary, making the comment that NMQAAC has no authority to review, approve or reject. That was not at all what the NMQAAC would be doing. It was not intended to approve or reject.

DR. LINV ER: No.

MS. HEINLEIN: It was more just to make sure --

DR. LINVER: We have knowledge.

MS. HEINLEIN: -- the committee would, then, have an understanding of what was being given alternatives.

DR. LINVER: We were to be apprised of any actions.

MS. HEINLEIN: So I see no reason to make any change on that.

DR. LINVER: Exactly, yes.

DR. KOPANS: Do you want to talk about just the comments or do you want to talk about the actual regulations?

DR. LINVER: Either.

DR. KOPANS: I may be missing someth ing here. I am a little concerned that one person can make the decision. Also, there is no time limit on this. How quickly will that decision be made?

I would support the last comment that if it is approved and there aren't any hazards -- and I can't even think of what

they would be -- that others should also be able to use it or do it that way.

MR. SHOWALTER: Do you want a response to the one person?

DR. LINVER: Yes. Charlie, could you respond?

MR. SHOWALTER: Ultimately, one person in FDA approv es everything that gets approved. It is just a question of how far down that delegation of authority goes. It is either the commissioner or the center director or, in this case, it is Flo, the division director. I don't know what you can do about that.

DR. KOPANS: What about, I guess, maybe an appeal process?

MR. SHOWALTER: There is always an appeal process.

DR. KOPANS: Should that be in this document, too?

MR. SHOWALTER: There is always staff review. There is always recommendations. The reality of what happens to an application is it comes into my group. I assign it to someone who gets to review it, to make a recommendation. I look at it. I do any revisions I want to do. I send it on to Flo. She looks at what everybody has done. So there is a lot of review. It is not just one person having --

DR. KOPANS: But the law says that it can be one person. You are saying what happens, but if somebody, 5 years from now, you are in a different position, someone says who is the --

MR. SHOWALTER: I certainly hope.

[Laughter.]

DR. KOPANS: The program director could theoretically, based on this law, do it by --

MR. SHOWALTER: Again, that is the case with any approval from FDA. You can't really write into a regulation the administrative process you used to develop an approval.

DR. KOPANS: But how about writing in that an appeal can be lodged or something? This doesn't even give room for an appeal.

MR. SHOWALTER: Well, any decision by FDA is appealable.

DR. KOPANS: By law?

MR. SHOWALTER: Yes, yes.

DR. LINVER: Ruth?

MS. McBURNEY: Yes. I do think that this provision does need to remain in there, especially in these changing technologies. We have a similar situation in the State where we cannot keep up with all the rules that we need to do. A lot of the changes in the technology and so forth would preclude someone from doing something, even though it is better.

We do handle those on a case-by-case basis, and the recommendations do go up a chain of command before they are

actually approved by the assigned person. There is an appeals process if it is denied.

DR. LINVER: Joel?

DR. GRAY: I would like to get a clarification from someone as to why certain wording was put in here, and that is under section (f), where other entities interested in similar or identical approvals must file their own application following the procedures of paragraph (c) of this section.

MR. SHOWALTER: Why was that put in there? That was put in there because the individual who wrote this, who shall remain nameless, was very, very conservative.

I am personally favorably impressed by some of the comments that said this should be broadened, and if it is a good idea, we ought to at least reserve the authority or the right to broaden the approval. I think that, in my view, is clearly the way to go. Obviously, that has to be vetted through the system.

DR. GRAY: I would definitely support that because what I see here is if something good happens, you are going to be overwhelmed with paperwork from people requesting --

MR. SHOWALTER: We may do it. I have pointed that out to the writer that I did not want to receive 10,000 applications for the same thing.

DR. KOPANS: What about the time limit on this, Charlie, on this review process?

MR. SHOWALTER: There is no time limit specified in the regulation. It is generally considered to be bad practice if you are a regulator to put a time limit on yourself that isn't imposed by statute.

I would not expect these to be anything dealt with in any way except a very timely way because it is silly not to, but we have not elected to put in that we shall rule on them in the 90 days or whatever.

DR. FINDER: Let me also just say about the time limits, the few cases that we have gotten, generally, they don't follow the rules as written. So we get a request, and then we have to write back to them and ask for information. Then, they send us some information, and this goes back and forth, but it is not so much that the decision-making process is long. It is the question of how long it is going to take them to get back to us with information.

DR. KOPANS: Couldn't you set a time limit from completion of all the necessary submissions or whatever, a response weill be received within 90 days or something?

I am just concerned. I know you guys have a lot of work, but there could be something out there that really is extremely valuable and you just don't get to it not because

it is malicious, but if there is no time limit put on, it might keep getting pushed to the bottom of a pile and to the detriment of women.

MR. SHOWALTER: I hear what you are saying. We could put a time limit in.

Now, carrying that out to its logical end point, what happens if we don't meet that time table? What I would not want to put in is that if we don't meet the time limit, you can go ahead and use it. I think that would be very dangerous. So the effect of having a time limit and we not meeting it is the same effect as not having a time limit.

MS. KAUFMAN: I think the time limit is a little tricki er than that, too, because it depends upon the technical difficulty of what somebody is requesting. If somebody is requesting something fairly simple, for example, I did my RT in the Philippines or something, which I think was the request, that is fairly easy to respond to.

On the other hand, if somebody says I have this wonderful new compression device that is completely different than anything you have ever seen before, you may have to do a little bit of research and look into it and that kind of thing.

I think that everybody needs to remember that these folks are public employees, and if you don't get what you consider

to be a timely response, you have the ability to write all the way to the President of the United States and file a complaint. I can assure you that when you start writing to higher levels, you get some response.

MR. SHOWALTER: We have a consumer complaint mechanism.

[Laughter.]

DR. KOPANS: Is that posted? I see no papers. We think the regulators protest too much.

DR. PATTERSON: But you could get it off the Internet.

MS. KAUFMAN: We have been there.

The second thing is, we discussed it in great detail, the issue of allowing other facilities to use previously approved variances, shall we say, for other things, and I believe that we agreed that, in many instances, they would do that; that we would already take out this. So I think we have already covered that in our April meeting.

DR. KOPANS: My only concern is "don't worry, trust us" has, in my experience, which is getting to be quite large now, not sufficient. You guys are wonderful. I don't know who is coming after you.

MS. KAUFMAN: I feel the same way about the regulated community.

DR. KOPANS: You are not trusting us. You are regulating.

MR. SHOWALTER: Dan, don't forget we are from the Government. We are here to help you.

DR. LINVER: In summary, the question that the FDA posed to us as a committee was or is there an adequate case for a change in the alternate standards as written, and if so, what changes should be made. I think the major issues, as I saw them, was the issue of whether any monitoring should occur after approval to make sure that these standards are at least as good as the standard approach, and secondly, what is the status of applicability beyond a single applicant.

I will open that up quickly for discussion, and then we will be done. I think we are done.

Penny?

MS. BUTLER: I just have a couple of questions for Charlie on the applicability issue, and this is analogous to the variance in process.

MR. SHOWALTER: Under the diagnostic X-ray standard where this was first used, yes.

MS. BUTLER: Right.

Is a variance issue to a single entity or is it once a single entity has applied for a variance, is it across the board?

MR. SHOWALTER: No. It is to a single entity, but the single entity in that case is a manufacturer. So I think, in that case, it would be inappropriate to apply it broader than a single manufacturer who applied for it because they are the ones who thought of it. Everybody else shouldn't be given the commercial advantage of that manufacturer who applied.

This is a little different where we are, in principle, talking about something that is a matter of public health or can be. It doesn't have to be, but in the case where you would want to make it broadly applicable, I would think that that would be the case. So you are not really concerned so much about commercial advantage. It is what is good for the patients.

DR. LINVER: Joel?

DR. GRAY: Is this similar, then, to the mechanism if one manufacturer gets an IDE or one institution or a 510(k) and that sort of thing, they all still have to go through the process?

MR. SHOWALTER: The way it is written right now, it is that way.

DR. GRAY: Okay.

MR. SHOWALTER: Yes.

DR. LINVER: Ed.

DR. HENDRICK: I have a question that may not actually be relevant to this, but in the larger sense, it is. If the advisory committee thinks the final rules need to be changed, say, across the board for all facilities, how do we handle that? Not through this mechanism, I assume.

MR. SHOWALTER: Oh, no. That would be handled through communication between the committee members and the exec sec who would presumably bring it up for discussion, put it on the agenda for a meeting, call a meeting, whatever. That is one way to handle it.

Another way to handle it would be to communicate amongst yourselves about something like that, but that is a little iffy, technically.

DR. HENDRICK: Right.

MR. SHOWALTER: So the best way is for the individual to communicate, do it at an open meeting, make a recommendation, and it gets into the system for change.

DR. PATTERSON: Charlie, there is a lot to communicate among yourself.

MR. SHOWALTER: That is what I said. It is a little iffy technically.

DR. HENDRICK: It would require rulemaking in the sense of drafting some modification, publishing it in the Federal Register.

MR. SHOWALTER: Yes, it would. Across-the-board changes would require all of that. Yes.

DR. LINVER: So is the feeling of the commi ttee that FDA should look into the possibility of allowing applicability beyond a single applicant? Is that the feeling of the committee?

Yes, Penny.

MS. BUTLER: The other question I have, in the beginning, it says that this applies to Federal agencies and State governments that are not accreditation bodies, and if a State applies for an alternative to one of the standards, based on their particular situation, for example, and it is approved by FDA, then if we open up this applicability, it could be readily picked up by other States without adequate review.

MR. SHOWALTER: I don't think there is a situation where a State needs to apply -- well, I mean, there are two situations. One is they want to apply a standard that is more rigorous. They can do that, anyway. They don't have to apply to us to do that.

I would think that they would have to make a very, very compelling case to apply a standard that is more lenient. I just can't imagine that being approved.

If it were approved under some circumstan ce, if that very compelling case were made, the scope of applicability would be limited in some case like that to the entity that applied. Because it is possible to open it up broader than that doesn't mean you have to, and in many cases, you wouldn't want to.

You would only do that if it made sense from a public health point of view or from an administrative point of view that this is sort of a trivial change. It is probably better, but I don't want to see 10,000 applying for it. So, okay, anybody who wants to can use it because it is really not that meaningful. Or, this is really important and everybody really ought to use this. So anybody can use it that wants to. Most things are not like that. Most things are going to be individual.

MS. BUTLER: Perhaps it may help me understand if you could cite some examples of situations you have already had, and I know you have gone through some of this before. I just don't recall.

It is very limited experience to this point. The one case that has completed the full process, and Charlie can help me out on this, perhaps, because he dealt with it, was from a facility in Korea, a military facility, who wanted to use technologists that were registered under the Korean

Technologists Society, but they had an individual in mind. Most of the documents they sent to us, many of them were in Korean that dealt with the Technologists Society requirements. It would have made it very hard for us to complete the 3-month review, I have to say.

What we wound up doing is s aying we can't make any sense out of any of this in terms of whether these requirements are similar to the ASRT requirements, but what we can make sense out of it is this individual they want to use is a well-trained individual, well-experienced individual, and we don't see any reason why we should worry about that individual doing mammography.

We approved a very limited scope approval for that individual to practice. That is the way that analysis went in that situation. That is the only one we have dealt with.

DR. PATTERSON: I am going back to under (f) where it is applicable under other entities or not under other entities. It makes a comment here that everyone else would have to apply except when the alternative standard is approved for manufacturer of equipment and any facility using that equipment. That, then, would be okay.

The question is, well, then why not open it up broader. You are trying to say that any manufacturer wouldn't have to apply for their alternative standard for their equipment.

It seems like you are getting back to why you don't have it on the other thing.

MR. SHOWALTER: I think that if it is a manufacturer that applies for something that is related to their particular equipment that it would be extremely unlikely that we would broaden it beyond that one manufacturer because they are dealing with a commercial interest.

The situation I was concerned about was a facility making an application and comes up with something that is clearly better than what we have now. I don't know what that is but a situation where we would sit back in our office and say, "Gee, I wish everybody would do it this way instead of the way it is in the regulations," but under the way that this was proposed, we would have to deal with this on a facility-by-facility basis rather than saying, "Okay, we have got one facility who applied. We can only approve their facility." I would like to be able to say that they had such a good idea that, in the interest of public health, we need to approve this for anybody to use.

It is not a commercial kind of thing at that point. It is more of a public health issue, and again, I don't have an example. I don't know what that is.

DR. PATTERSON: I think that if you do open it up or broaden it, you are going to have to make sure that you are protecting the individual equipment companies.

MR. SHOWALTER: You are absolutely right, and we are very sensitive to that.

DR. LINVER: Thank you. That's it.

DR. PATTERSON: Thank you, Mike.

We are adjourned until tomorrow m orning at 8Êo'clock. We have a lot under the accrediting bodies that we do have to cover tomorrow before people start leaving.

[Whereupon, at 9:35 p.m., the proceedings were recessed, to be resumed at 8:00 a.m., Wednesday, January 15, 1997.]

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